Exhibit B

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

JO HUSKEY AND ALLAN HUSKEY,	:	
Plaintiffs,	:	CASE NUMBER
v.	:	2:12-cv-05201
ETHICON, INC., ET AL.,	:	
Defendants.	:	

TRANSCRIPT OF TRIAL - DAY SEVEN

SEPTEMBER 02, 2014

BEFORE THE HONORABLE **JOSEPH R. GOODWIN,**

UNITED STATES DISTRICT JUDGE

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I N D E X

PROCEEDINGS had before The Honorable Joseph R. Goodwin, Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on September 02, 2014, at 9:15 a.m., as follows:

COURT SERVICES OFFICER: All rise.

(The jury entered the courtroom at 9:15 a.m.)

THE COURT: Good morning, ladies and gentlemen.

RESPONSE: Good morning.

THE COURT: We are ready to resume the trial. I have been advised that you were told of Mrs. Fields' tragic loss. I know you join me in extending the Court's sympathy to her and to her family. Mrs. Fields is excused as a juror.

We will continue the trial with the eight remaining jurors.

Mr. Wallace?

MR. WALLACE: Your Honor, with your permission, I just want to move this screen.

THE COURT: You may.

Ladies and gentlemen, the plaintiffs having rested, we now turn to the defendants. Call your first witness.

MR. THOMAS: Thank you, Your Honor. Defendants called Dr. Shelby Thames.

THE DEPUTY CLERK: Raise your right hand.

(**SHELBY F. THAMES, Ph.D.**, HAVING BEEN DULY SWORN, TESTIFIED AS FOLLOWS:)

THE WITNESS: I do.

THE DEPUTY CLERK: Thank you. Please take the witness stand.

(DIRECT EXAMINATION OF SHELBY THAMES, Ph.D. BY MR. THOMAS:)

Q. Good morning, Dr. Thames.

A. Good morning, sir.

Q. Would you tell the jury your name, please.

A. My name is Shelby Thames, T-H-A-M-E-S.

Q. Dr. Thames, are you comfortable there?

A. Yes, sir.

Q. There's some water there if you need some.

A. Thank you.

Q. Where do you live, Dr. Thames?

A. I live in Hattiesburg, Mississippi.

Q. And where do you work?

A. I work at the University of Southern Mississippi, although I was recently retired. I went back and started employment again.

Q. And what's the name of the building where you work?

A. The Polymer Science Research Center.

Q. And does the Polymer Science Research Center have a name?

A. Yes, it does.

Q. And what is the name of that research center?

A. The Shelby Freland Thames Polymer Science Research Center.

Q. And how long has it been named the Shelby Freland Thames Polymer Science Research Center?
A. I believe since about 1998, sir, when it was built.
Q. And is that the same Shelby Thames as you?
A. Yes, sir.
Q. Why is it named after you?
A. Well, they had to have somebody to name a building after, I guess, and they just picked me. I was very pleased, of course.
Q. Why are you here today?
A. I'm here to testify on behalf of Ethicon and to tell you about the chemistry and the polymer science of Prolene.
Q. Dr. Thames, did you help me prepare a PowerPoint presentation to help the jury understand your credentials and your opinions in this case?
A. I did, sir.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

THE WITNESS: Thank you.

BY MR. THOMAS:
Q. Dr. Thames, I've handed you Defendants' Exhibit 10351, which is entitled "Curriculum Vita for Shelby Freland Thames, Ph.D." What is that document?
A. This is a document that describes my history of employment, the activities that I've been involved in, and the

things that I've done over the years that I've been at Southern Miss.

MR. THOMAS: Your Honor, I would offer Dr. Thames' curriculum vita into evidence.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(DEFENDANTS' EXHIBIT D-10351 WAS RECEIVED IN EVIDENCE.)

(The document was published to the jury.)

MR. THOMAS: Slide 1, please, Jamey.

BY MR. THOMAS:

Q. Dr. Thames, tell us a little bit about your educational background, please.

A. I received a Bachelor's Degree in chemistry from the University of Southern Mississippi, and that was followed by a Master's Degree in organic chemistry from Southern Miss. And I traveled to Knoxville to receive a Ph.D. in organic chemistry where I minored in analytical chemistry.

Q. Would you tell the jury, please, what organic chemistry is?

A. Organic chemistry is the study of organic compounds which are essentially made of carbon and hydrogen as the main components.

Q. And would you tell the jury, please, what analytical chemistry is?

A. Analytical chemistry is the study of equipment and

techniques and methods for evaluating chemicals. In other words, once a scientist designs the polymer and synthesizes it in the laboratory, they have to determine whether or not they actually made what they thought they made. So in order to do that, we use analytical tools in order to determine the structure of chemical compounds, how much something is present, what it is, and so forth and so on. That's analytical chemistry.

MR. THOMAS: Next slide, please, Jamey.

BY MR. THOMAS:

Q. Can you tell the jury a little bit about your work experience, please.

A. Well, after graduating from the University of Tennessee, I went to -- directly to Southern Mississippi to work in the chemistry department. My professor called me in and said, "You need to come back to school here and to work," and I did so and joined in the chemistry department where I became associate professor of chemistry from 1964 to '71.

And then the president asked me to be vice president of research for the Pan American Tung Research and Development League and I did that.

And I was also chair and -- of the Department of Polymer Science at Southern Miss. And I founded the Department of Polymer Science at Southern Miss in 1969.

1971, they asked me to be the dean of the College of

Science. We took that responsibility and transformed it into the dean of Science and Technology, and at that time I, of course, continued to be the professor of polymer science.

In 1982 to '86, I was a professor of polymer science.

From 1986 to present, I am called the Distinguished University Research Professor of Polymer Science. We have added engineering so it's now --

THE COURT REPORTER: I'm sorry.

THE WITNESS: We have added engineering to our program. So it's now "Engineering" added to the title.

BY MR. THOMAS:

Q. What does a polymer scientist do?

A. A polymer scientist studies polymers, of course, and a polymer is a molecule, "poly" meaning mini, "mer" meaning single units. And I like to liken that to a chain, each link in the chain is a mer unit, one unit. If you begin to link those links together, you can have two, five, ten, a thousand, a hundred, and that makes your polymeric chain.

And so if you do that with molecules, then you have a polymer. And polymers have some unique characteristics because they're huge molecules. You can design them to do various things. You can make them strong, you can make them tough, you can make them soft. So you can make them do almost anything you want them to do, but you have to understand the chemistry behind it. And I have a saying that's more or less

coined in a way, and it's the saying, "It's all in the chemistry." So you have to know the chemistry.

Q. Dr. Thames, have you taught polymer science throughout your career?

A. Yes, sir, I have.

Q. And to whom have you taught, what --

A. To undergraduate students who are beginning students in the university system, to graduate students who come to learn, to attain Ph.Ds and master's degrees from my program, to post-doctoral fellows who have earned a Ph.D. at other institutions and want to learn about polymer science because they didn't learn it any or enough at wherever they were educated. So they come to us, and they work with us, and we teach them polymer science.

Q. Have you continued to use your analytical chemistry minor in your work?

A. Yes, sir, I have.

Q. And how have you done that?

A. Well, the area that we are strong in is designing materials, designing polymers. Once you design them on a piece of paper, then you set out to actually synthesize that polymer, or make it. And so you develop a protocol for how you think you should make that polymer, you execute that protocol in the laboratory, and then once you achieve a product, you say, "Well, did I really make what I wanted to

make?"

And then that's when you take it and you use the analytical tools we were talking about to determine whether you indeed did make what you wanted to make. And so that's how we do things. And then we test the product to see if it has the properties that we want.

Q. Have you developed a specialty in polymer science over the 50 years that you've been a polymer scientist?

A. Yes, sir, I have.

Q. And what is that specialty?

A. That specialty is in coatings, and one simple term of a coating is with pigments which would be paint. But the beautiful part about a coating is that it has to adhere, so you have to have an understanding of adhesion, it has to have physical properties that give it longevity, and in a multitude of environments. So it's a very fairly complex kind of polymer system, but it's an awful lot of fun to study and to work with.

Q. Of what importance is your specialty in coatings in your work that you've done in this case?

A. Well, what we do in coatings, of course, is we design a polymer and we make a polymer, and then we use analytical tools to determine if it's what we made, and we study the structure-property relationships, and by structure-property relationship, I mean that if you change the structure of a

molecule, you will change the properties. So if it doesn't have a particular kind of property that you want, then you see about changing the structure to get the property that you wish.

And so what we've done here in terms of studying a Prolene is to determine what the properties were, to look at them and to see if they were sufficient for its intended use.

Q. And you indicated you've done research over the years?

A. Yes, sir.

Q. Can you give the jury an idea of some of the kinds of polymer research that you've conducted?

A. Well, I've studied -- I've done quite a bit of work in proteins, in particular, in soy proteins, and adhesives. I've done a lot of work in vegetable oils and lipids and fats. I've done quite a bit of work in biological materials from agriculture. I've done work from hydrogen carbon materials, I've done work in powder coatings, polyurethanes and acrylic polymers and oil-based polymers. And it pretty much covers the gamut of the kind of work that I've done and been -- had fun doing it.

Q. Prior to your work in this case, had you done any research in polypropylene?

A. I had done no research in polypropylene, no, sir.

Q. Have you taught any of the chemical characteristics of polypropylene?

A. Yes, I have.
Q. And over how many years?
A. Several. You can look at my hair and I've taught courses a long time.
Q. Now, does the Shelby Freland Thames Polymer Science Research Center have a laboratory?
A. Yes, sir. The building is -- has many, many laboratories. As a matter of fact, it only has two small classrooms, and the remaining are laboratory or office spaces for faculty members and staff members.
Q. I put up a slide there. Is that the Shelby Freland Thames Polymer Science Research Center?
A. Yes, sir, that's the front of it.
Q. And what is in that building?
A. Well, it's about 106,000 square feet, and it's offices, laboratories, a multitude of different kinds of equipment, analytical tools. We are blessed to have a very finely equipped facility. I would estimate that we probably have $25 million of analytical tools in that facility.
Q. And do you have those tools available to you for your work?
A. Yes, sir.
Q. And when you do work that's not related to the university, do you pay for that work?
A. Yes, sir.

Q. Now, has the Shelby Freland Thames Polymer Science Research Center ever received any research funding from Ethicon or Johnson & Johnson?

A. Not that I'm aware of. Certainly not for me.

MR. THOMAS: Next slide, Jamey.

BY MR. THOMAS:

Q. Let's talk a little bit about your professional affiliations.

A. Yes, sir.

Q. Tell the jury about these organizations.

A. Well, the Waterborne Symposium is a symposium that was developed by myself and two other colleagues to exploit the knowledge base behind waterborne polymers, and it's been running now -- we have that symposium every year, and I think it's in its 41st year this year.

I've been a member of the American Chemical Society my entire career. It's the national organization of chemists. I've taught short courses for all of them. I've given presentations before them. So I've been extensively involved with them.

And then a couple of organizations of which I'm basically just a member is the American Institute of Chemists and the American Association of Advancement of Science, and there's others but I didn't bother you with them.

Q. And have you received any honors in your field?

A. A few.
Q. I put up a magazine cover from 2002, person of the year, people of the year from *Modern Paint & Coatings*. Tell the jury about that, please.
A. Well, this particular journal -- or it's not a journal. Actually, it's more like a magazine, but it's printed by the coatings industry, and I was pleased to see that they elected me to be one of the people of the year in 2002.
Q. Okay. Do you hold any patents?
A. Yes, sir.
Q. How many patents do you hold?
A. Approximately 40.
Q. Briefly describe some that relate to your work in polymers.
A. Well, there's a soy protein adhesive that we have patents on, and what we found is that we can make an adhesive that holds fibers together, particle board fibers together, that really outperforms other adhesives that are used, and it's a green product. It's made essentially from all agricultural or green materials, whereas most of the adhesives that's used in the past have been made from petroleum and, therefore, from oil-based substrates and, therefore, they were not green, as per se.
Q. Has any pharmaceutical or medical device company ever provided financial support for your research that led to these

patents?
A. No, sir.
MR. THOMAS: Next slide, please.
BY MR. THOMAS:
Q. You've also made some publications and presentations?
A. Yes, sir, I have, sir.
Q. Tell the jury a little bit about your publications.
A. Well, I have approximately 169 publications in journals and so forth over the years, and they've involved the research work and the writing of documents to describe the work that we've done in our laboratories and so forth. And then beyond actually having them published in print, many times you're asked to give presentations, and I've presented more than 150 presentations on the work and the activities that I've been involved in as a polymer scientist.
Q. How many of these publications and presentations have been on polymers?
A. There may be one or two that's not, but I can't remember, but the vast, vast majority of them have been in polymers, sir.
Q. Now, Dr. Thames, have you testified from time to time over the last several years as an expert witness?
A. Yes, I have, sir.
Q. And what do you charge for your time?
A. $375 an hour.

MR. THOMAS: Your Honor, I offer Dr. Thames as an expert in the field of organic chemistry, polymer science, and analytical chemistry, specifically to discuss Prolene, the chemical and physical properties and its propensity or lack of propensity for degradation and oxidation.

THE COURT: Any voir dire?

MR. KUNTZ: No objection, Your Honor.

THE COURT: All right. You may offer opinions in that area.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q. Dr. Thames, a moment ago you described what a polymer is. What is a polypropylene polymer?

A. It is a polymer made from the single link which is called propylene. So we have a single monomer called propylene, and if it reacts with itself like a link in a chain, it's called polypropylene.

Q. Okay. And is the polypropylene molecule a -- a diagram that you can make, that you can show the jury?

A. I'd love to.

Q. Would you --

MR. THOMAS: Your Honor, may he step down and show the polypropylene molecule on the white board?

THE COURT: Doctor, you may do that. My caution is that both the jury and the court reporter need to see and hear

you.

THE WITNESS: Yes, sir.

THE COURT: All right.

MR. THOMAS: Thank you.

(The witness left the stand.)

THE WITNESS: I spoke of a single link being propylene, and I'm going to draw the chemical structure of propylene.

That would be your single link in a chain, and if you take that molecule and add it to itself, I can -- one of the ways I like to describe it is we probably all stood dominoes up on the end of the table, and then we have tapped the one at the far end and they continue to fall, one on top of the other, and then make a stream of dominoes. That's the way an addition polymer like this forms.

So we take this molecule, and we initiate it with an initiator, and it produces polymer called polypropylene.

BY MR. THOMAS:

Q. Here's a fresh one.

A. Good. Thank you.

Draw an arrow to show what it will be.

Now, this molecule can become so huge that it can have a mass of 3 to 400,000, and the way you determine the mass, the weight, is you add up the elements that are there. Carbon weighs 12 anatomic mass units.

THE COURT: Mr. Thomas, would you not get between the court reporter and the witness? Thank you.

THE WITNESS: Carbon weighs 12 atomic mass units and hydrogen weighs 1. So each of these carbon weighs 12, each hydrogen weighs 1. You add all those up and you think about how many of them you would have to have to have over 300,000 molecular weight. It's a huge, long polymer chain. That's why I used X to show that it's many, many, many, many of these segments that are present in polypropylene.

Now, this is propylene. This is polypropylene polymer.

Q. Dr. Thames, what's the significance of the fact that it's only carbon and hydrogen atoms?

A. The molecule -- oxygen and hydrogen and sulphur and nitrogen are polar molecules. That means that they have a distinct electrical environment where one end of the molecule is positive, the other end of the molecule is more negative. Kind of like a magnet. And what that means is that in the case of those polar molecules, polar chemical reagents have an affinity to attack them. In other words, negative attacks positive.

Where if you have carbon and hydrogen molecules, there are no polar groups. It means it doesn't like water, water doesn't like it, it's hydrophobic. It has a phobicity to water. Doesn't care for it. There is no tendency or

rationale for why a polar molecule would attack this and destroy it.

So that's part -- that's -- I hope that answers your question, Mr. Thomas.

Q. Would you take your seat, please?

A. Yes.

(The witness resumed the stand.)

BY MR. THOMAS:

Q. Dr. Thames, as a polymer scientist, are there things that can disrupt a polymer?

A. Yes.

Q. And tell the jury about the disruption of the polymer chain.

A. Well, polymers in general can be disrupted in several ways.

One is by heat. You can actually put enough heat to it that you will destroy it thermally.

One is by pH changes, going from acid to base, attacked by acid or attacked by base.

The other is by light, UV light being impinged upon a sample where it excites the molecule and causes a chemical reaction to take place that would degrade the polymer.

And the other is by water. Just simply because of its -- a polymer, some polymers have a tenacity to attract water. Water can attack them.

So those are the four, four general categories.

Q. Dr. Thames, the jury has heard a word over the last several days about a chemical being inert. What does inert mean?

A. Inert means that it is nonreactive. And in the general sense when you just say "inert," you're saying it's non-reactive to everything unless you specify what it is not inert to.

Q. Okay. And is there anything in chemistry that's totally inert?

A. Not that I'm aware of.

Q. All right. Can you give the jury some understanding of how polypropylene is used in a real-world context?

A. Yes, sir.

(The document was published to the jury.)

THE WITNESS: Well, for instance, we see a number of objects made of polypropylene. They are made of that because they are durable, because they're tough, and you notice the hand holds some little -- could be Skittles, I'm not sure. What's important is the box with the top on it. That's a self-hinging box.

And polypropylene is -- has such durability, such toughness that it can actually form as a hinge, and you can imagine the kind of mechanical processes and stress that's on the sample like that, because bending it -- you can take a

paper clip, for instance, and bend it till it breaks. Well, you can open and close this box many, many, many times and you don't sever the polypropylene.

BY MR. THOMAS:

Q. Dr. Thames, the jury has heard about the Ethicon brand of polypropylene known as Prolene. What is Prolene?

A. Prolene is a formulated product of polypropylene and some selected additives that are placed in the polypropylene mass or medium to provide certain characteristics to the molecule.

Q. Dr. Thames, what makes Ethicon's Prolene different from other polypropylene used by other medical devices?

A. The nature of the additives that are added.

MR. THOMAS: I have put up on the screen DX-23600. May I approach, Your Honor?

THE COURT: You may. Is there an objection to the --

MR. KUNTZ: No objection.

THE COURT: All right.

MR. THOMAS: This may have been received with Dr. Guelcher. Certainly used it with him. I apologize.

THE COURT: If it hasn't been received, let me know, because I'm just going to leave this on, otherwise.

MR. THOMAS: I'll offer it into evidence, Your Honor, in the event it hasn't.

THE COURT: All right. It may be received.

(DEFENDANTS' EXHIBIT D-23600 WAS RECEIVED IN EVIDENCE.)

BY MR. THOMAS:

Q. The jury saw this document earlier with Dr. Guelcher. You are familiar with this document?

A. Yes, I am.

Q. And on the board is the discussion of the five additives --

A. Yes, sir.

Q. -- to Prolene? And tell the jury the significance of those five additives to Prolene polypropylene.

A. Okay. You need to keep in mind that we take polypropylene and add to that these five materials.

The first material is called calcium stearate. It is a calcium salt with stearic acid. It's a lubricant to help reduce tissue drag and promote tissue passage.

The second additive is dilauryl thiodipropionate. It's abbreviated DLTDP, and it's added as an antioxidant to improve long-term storage of the resin and fiber and to reduce the potential oxidative reaction with ultraviolet light.

The second is Santonox R, and this is an antioxidant which promotes stability during the compounding and extrusion of the fiber from the extruder which is a heated extruder so it needs to have protection from that, as far as thermal degradation is concerned, and it will -- it will halt any thermal degradation that might occur.

The next is Procol LA-10. It's a lubricant again, to

help reduce tissue drag and promote tissue passage.

And the last is CPC pigment, which is a copper-based colorant to provide enhanced visibility to the TVT device which is blue.

Q. Dr. Thames, have you learned about how this Prolene polypropylene is made?

A. Yes, sir, I have.

Q. Could you describe that briefly to the jury so they understand how this material is made?

A. Sure.

First of all, they take the polypropylene polymers, which are made by -- it's been made by the same company since their existence. And they take this polymer and they put it in an extruder. It's a device that can be heated, and the extruder is heated and it's blended with an auger, and that blending takes place. And then you add these five ingredients to it, and they maintain it in that extruder under a blending process until a sufficient time has been -- has come about that you get good distribution of materials. And then you turn it into the extruding step --

MR. KUNTZ: Your Honor, can we approach for a second?

THE COURT: You may.

(The following occurred at sidebar.)

(A sidebar discussion was held off the record.)

MR. THOMAS: Before that document would go back to

the jury, Your Honor, we need to redact a sentence.

MR. KUNTZ: But it's up there right now -- this document is up on the screen right now, with "regulatory" and "FDA" all over it.

THE COURT: Well, take it down right now, and if it ever happens again, this whole case is --

MR. THOMAS: Yes, Your Honor.

(Sidebar concluded.)

THE COURT: All right, sir.

BY MR. THOMAS:

Q. Thank you.

Dr. Thames, could you continue discussing the manufacturing process, please?

A. Sure.

After you've appropriately blended the polypropylene with these five ingredients, there is a barrel at the end of the extruder that has the diameter of the fiber that you want to extrude, and there's several of them, and I kind of liken it to, if you've ever seen hamburger go through or pressed through an extruder and it comes out in small strings, that's kind of what we're talking about here. And so the fibers are extruded in that way.

And those fibers then are used, that is now Prolene. We took polypropylene and we added the five ingredients and we then made Prolene.

Q. Does the extrusion process leave any fingerprint or marks on material?

A. Yes, sir. When it goes to the barrel, the barrel is not precisely smooth, and you'll see some lines in it, but we call those extruder lines.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

I'm turning this off until we --

MR. THOMAS: I understand.

BY MR. THOMAS:

Q. Dr. Thames, I have handed you what's been marked as Defendants' Exhibit 30884. It's an article by Timothy Liebert and others published in the *Journal of Biomedical Material Research*, titled "Subcutaneous implants of polypropylene filaments."

Did you review this article in connection with your work in this case?

A. I have.

Q. Do you consider it to be authoritative on the issues it discusses?

A. Yes, sir.

MR. THOMAS: Okay. And, Your Honor, I offer Defendants' Exhibit 30884 as a learned treatise.

MR. KUNTZ: No objection, Your Honor.

THE COURT: Very well.

(DEFENDANTS' EXHIBIT D-30884 WAS RECEIVED IN EVIDENCE.)

MR. THOMAS: May I publish it to the jury?

THE COURT: You may.

(The document was published to the jury.)

MR. THOMAS: Thank you, Your Honor.

THE COURT: With the --

MR. THOMAS: We will check it.

THE COURT: All right.

BY MR. THOMAS:

Q. What -- tell the jury what Liebert and others did in 1976.

A. These gentlemen studied Prolene, and they -- and also polypropylene that was unstabilized. That's important to determine the distinction. Prolene is stabilized with these antioxidants, and we put those ingredients in to perform a particular function. You can just take polypropylene and not stabilize it and then that's another species, but it's different from the stabilized species.

And they performed infrared spectra and mechanical testing of the implanted and non-implanted filaments, containing an antioxidant, and showed that there were no changes in the physical or chemical properties as a result of implantation.

And, of course, these results support the fact that the changes observed for pure implanted filaments are due to

oxidation rather than diffusion. What they mean by pure filaments is that they didn't have any antioxidants. They used -- they used chemicals A and B.

In the case of A, there were no antioxidants put in them. In the case of B, the materials here, there were antioxidants put in them. And so they're different in that respect. They're looking to determine whether or not the antioxidants did the job and when they didn't have them, what happened to the system.

Q. And what did Liebert find?

A. Well, they found that when they used the antioxidants as prescribed in the Prolene formulation, that there were no changes in molecular weight, there was no oxidation, there was no adverse effect on the Prolene fiber.

Q. And what has Ethicon done with its Prolene polypropylene to add antioxidants to it to protect against oxidation as found in Liebert?

A. Well, they've added antioxidants, and the two antioxidants we talked about were Santonox R and dilauryl thiodipropionate, DLTDP, that material that we talked about.

Q. Dr. Thames, what is degradation?

A. Degradation is a change in physical property such that a material cannot and does not provide the same kind of property that it was intended to provide or the same function it was intended to provide.

Q. And what kind of changes happen in a polymer or polypropylene that would cause it not to perform as it intended?

A. Well, if polypropylene were -- underwent some form of degradation which caused it to change its molecular weight, in other words, when we talk about a huge molecule having over 300,000 molecular weight, if something happened to begin to chop that molecular weight up, and rather than having very long and tangled polymers which are durable and strong, you would have short, choppy polymers, and they would lose their physical properties. So breaking and cleaving of these chemical bonds I've described up here would be a form of degradation.

Q. And what is tensile strength?

A. Tensile strength is the -- if I take a string in my hand and I pull it and I pull it and I pull it and I pull it, and if I were able to measure the force, the point at which it breaks, the amount of force required to break it, is its tensile strength value.

And we have instrumentation in our laboratory that you could put all sorts of polymers in and at very precise measurements, and we used ASTM, American Society of Testing Methods, to -- as a protocol for how you go about doing that, and you stretch a fiber and you stretch a fiber, stretch a polymer, any kind of polymer, and you determine what force is

required to cleave or break the polymer. And that's called ultimate tensile strength, meaning -- ultimate means that's the tensile strength at which it breaks.

Q. And what is toughness of a polymer?

A. Toughness?

Q. Yes.

A. You have to include another characteristic of polymer before you can answer that question, and it's elongation. During the time that we are pulling this polymer out under this stress, it's elongating, it's elongating, it's like a rubber band. You pull, pull, pull, pull, pull. And at the time the polymer breaks, you measure the original length that you started with and the final length that you have and you measure the percent elongation that occurred during that time. So you have two features to look at, is the strength and the elongation.

And the area, if you plot that as stress and strain -- we'll do it this way, you would look at a chart this way. This would be stress and this would be strain or elongation. If you plot the curve like so, the area under that curve is a measure of toughness.

MR. THOMAS: Let's get the next slide please, Jamey.

(The document was published to the jury.)

BY MR. THOMAS:

Q. Dr. Thames, you prepared a graph to show the jury the

stress-strain curve of polymer types?

A. Yes, I have.

Q. Would you explain that to the jury, please?

A. Yes. First of all, remember the stress is the vertical axis, that's how much you -- tug you put on it. The strain or elongation is the horizontal axis. And I've shown in red a polymer that would be strong but not tough. And you would have to pull it, pull it, but finally when it broke, it would snap down, and the dotted line would be the ultimate elongation of that particular polymer.

Let's go down to the green one. The green one here doesn't require much stress at all to stretch it, and it stretches a long, long way. So it's not strong and it's really not tough. It's just easy to extend, doesn't take much, and gets kind of like a weak rubber band.

The one in the middle, in blue, is the polymer type that would be strong and tough, where you had to put a sufficient amount of force to stretch it, but at the same time, while it stretched, it elongated a significant amount before it finally broke.

Q. Okay. And where does -- where does Prolene polypropylene fall in this spectrum of stress-strain curve of polymer types?

A. In the strong and tough category.

Q. And what does that mean relative to other polymers?

A. Well, that it -- it, by virtue of its chemical structure

and so forth, is a strong and tough polymer system. It's not brittle. And it's not just a rubber-band-type material with not very much strength to it.

So it's a good composite between the two. It's designed to be -- have a good series of properties, between strong and not tough polymer or not strong and not tough polymer system.

Q. Dr. Thames, a moment ago we were talking about molecular weight.

A. Yes, sir.

Q. And we were talking about degradation. How does degradation of Prolene -- strike that.

How does degradation of polypropylene affect the molecular weight of polypropylene?

A. Degradation would cleave the polypropylene chain, like we've drawn on the chalkboard here, cleave that chain. And if you cleave that chain, you're going to -- you're going to reduce the tensile strength, and the reason behind that is that -- we've all made spaghetti, and when you put it in the colander, you notice that the spaghetti is all entwined and entangled, and if you just try to take one piece of spaghetti from the end and pull it out, just by itself, it's almost impossible to do that, and that's because you've got entanglement, so forth.

And what happens is the polymers are the same way.

They get their structures entangled, and so when you begin to pull them, they slide across each other. And they have a phenomenon of attraction that's referred to in the chemical profession as van der Waals force, it's V-A-N D-E-R W-A-A-L-S. That means that attractive forces between molecules.

Well, if you cut a molecule up into small pieces, you reduce the ability to have significant van der Waals forces and you lose your tensile strength. Your properties decline, plummet, they go down.

Q. When you break the molecules up into small pieces, what happens to the molecular weight?

A. The molecular weight goes down.

Q. And do you have to have a decline in molecular weight to have a change in the chemical composition?

A. Yes. And in this particular case we're talking about here.

Q. And tell the jury why that is.

A. Well, I think I just did. That was the explanation I was trying to make, is that when you have a change in molecular weight, you're reducing the ability for van der Waals forces to interact with each other, you've got shorter chains and, therefore, you're going to have less ability to -- it's not going to be as strong as it was at one time.

Q. Dr. Thames, have you analyzed yourself Prolene polypropylene?

A. I have.
Q. And have you analyzed yourself explants of humans --
A. I have.
Q. -- who have had Prolene polypropylene?
A. Yes, sir.
Q. And have you reviewed the work of others of explants of Prolene polypropylene?
A. I have.
Q. Have you ever found in research in a controlled experiment a decrease in molecular weight in explanted Prolene polypropylene?
A. No.
Q. And what does that tell you as a polymer scientist if there's no decrease in molecular weight in Prolene polypropylene?
A. If there is no decrease in molecular weight, there's no degradation of the polypropylene, in this case, Prolene.
Q. Have you also reviewed work by Ethicon studying Prolene polypropylene?
A. I have.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:
Q. Dr. Thames, I've handed you what's been marked as Defendants' Exhibit 23228, titled "Seven-Year Dog Study."

A. Yes, sir.
Q. Have you reviewed that in connection with your work in this case?
A. I have.
MR. THOMAS: Your Honor, I'd offer this exhibit into evidence.
THE COURT: May I see you at sidebar just one second?
(The following occurred at sidebar.)
THE COURT: This appears to be about a 50-page exhibit. Is counsel for the defendants representing to me that the initials FDA or the Federal Drug Administration appears nowhere in this document?
MR. THOMAS: Not to my knowledge, Your Honor.
THE COURT: I'm asking you if you're making that affirmative representation? I'm not -- it's happened twice. I will take a ten-minute break if you want to look through it, or if you want to go on to something else. Otherwise, if it's in here, I'm going to sanction you if it is, a very large amount of money, if it's introduced by accident.
MR. THOMAS: I understand, Your Honor.
THE COURT: So what do you want to do? Do you want to take a break and look at it?
MR. THOMAS: Yes, I do, Your Honor.
THE COURT: All right.
(Sidebar concluded.)

THE COURT: Ladies and gentlemen, I think that we've done very well. We haven't had to take very many unscheduled breaks. This is a time when we have to take one.

Ten-minute break -- make it 15, and we'll look and see how the morning goes. Do a 15-minute break.

I hope you enjoy that healthy stuff that's back in the jury room. And I'll call you back when we're ready.

Court stands in recess.

(The jury left the courtroom at 10:03 a.m.)

(A recess was taken at 10:03 a.m.)

(The jury entered the courtroom at 10:22 a.m.)

THE COURT: Okay. Mr. Thomas.

MR. THOMAS: May I proceed, Your Honor?

THE COURT: Yes, sir.

BY MR. THOMAS:

Q. Dr. Thames, before the break I was asking you about defendants' exhibit 23228 which is titled *Seven Year Dog Study*. Did you review this document in connection with your work in this case?

A. Yes, I did.

Q. And you relied on it for some of the opinions you have in this case?

A. Yes, I did.

MR. THOMAS: Your Honor, I'd offer into evidence defendants' exhibit 23228.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(Defendants' Exhibit 23228 received in evidence.)

BY MR. THOMAS:

Q. Dr. Thames, what is the *Seven Year Dog Study*?

A. A study where a number of dogs were used to implant Prolene into the dogs and they were maintained over a period of a number of years, in this case seven years, and at intervals some of the dogs would be sacrificed. The sutures, the Prolene sutures that were implanted in the dog would be removed and would be evaluated, evaluated for molecular weight, evaluated for tensile strength, evaluated for elongation, and other features like the infrared spectroscopy would be done and so forth. And at the end of seven years the last dogs were used. And this study compiles data that was collected in that manner for over a seven year period.

Q. Dr. Thames, the jury has already heard a little bit about this study in the examination of Dr. Guelcher last week. I want to direct your attention to page 115, excuse me, 116 of this document. Jamie, could you pull that up, please?

Do you have that in front of you, Dr. Thames?

A. Yes, sir.

Q. Right in the middle of the page there's a heading called optical microscopy and scanning electron microscopy. Are those analytical chemical techniques?

A. Yes, sir.
Q. Can you tell the jury what optical microscopy and scanning electron microscopy is?
A. Sure. Optical microscopy is looking through a microscope with no unnecessary additional energy input into it, with good lighting assistance and so forth, typical microscope, but a sophisticated one and fairly expensive.

Scanning electron microscopy is a technique in which a sample is placed in an instrument, it's bombarded with an electron beam, and that electron beam then is reflected on to a mirror of sorts and that produces an image, and that image is of a surface that it's looking at. It can be very high magnification, five, six, seven thousand times, and it's a good way of looking at fine structure of a material.
Q. Under the heading conclusions, the second bullet point reads, "Degradation in Prolene is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."

What does that report mean from a scanning electron microscopy perspective?
A. Well, it suggests and states that the surface of the Prolene explant that they saw cracks and that it would -- they think it will continue to crack.
Q. And as a polymer chemist, if there is degradation in terms of cracking in the polypropylene, what would you expect

to find?
A. You would expect -- you would not only expect to find, you would find a loss of, and they allege that this is degradation, a loss of molecular weight, and you would change different properties, tensile strength and elongation would be changed from the normal not exposed sample.
Q. Now, let's go back to the page 115 right before and under IR and IR microspectroscopy. Could you tell the jury what that is, please?
A. IR microscopy is infrared microscopy where an electron beam hits the sample, reflects back to a sensor and it shows the picture of the surface that you're looking at. Microspectroscopy is looking at a very, very fine small point under a microscope. In other words, if you find an area under a microscope, you can zero in on a very, very small area and run an infrared spectra or see the spectra of that particular compound, whatever that might be at that pinpoint type area.
Q. And this report is October 15, 1992, is that right?
A. Yes, sir, that's correct.
Q. And that's seven years into the test?
A. Yes, sir.
Q. Under the second paragraph, under the IR and IR microspectroscopy, it reads, "IR microspectroscopy was used to examine cracked areas in Ethilon, Novafil and Prolene." Just for the jury's benefit, what are Ethilon and Novafil?

A. They're not Prolene, they are different structures of materials, sir.

Q. It says, "IR spectra obtained for cracked Prolene specimens, paren, figure A, showed possible evidence of slight oxidation, paren, a broadened weakened absorbance at about 1650 C M minus one."

What does that mean to you as a polymer chemist?

A. Well, when I see the term *shows possible evidence*, that means it's not clear and not concise, that it's possible. Most anything is possible. Then they say a broadened weak absorption at about 1650 reciprocal centimeters. My mind would jump to the fact that the 1650 reciprocal centimeters is an absorption frequency in the infrared that would be an area where you would expect to see proteins perhaps, and that more likely than you would see proteins then, of course, you would see any degradation from polypropylene or Prolene. So my feeling is that we are looking at something that's not Prolene, it may even be an acid salt, but not Prolene.

Q. How would proteins get on to this suture?

A. Proteins are in flesh. When they take the explants out, and they didn't clean these in any way, they didn't put them in any sort of chemicals for anything, they're on flesh, you would expect to see proteins from the flesh.

Q. Down the next paragraph there's a heading for IV and GPC. What is GPC?

A. Gel permeation chromatography.
Q. Tell the jury what GPC does.
A. GPC is a standard method for determining molecular weight. If I wanted to know the molecular weight of a polymer, I would use the instrument called the gel permeation chomatograph. What you do in a situation like that is you dissolve the polymer in a solvent, typically halogenated hydrocarbon. You inject it into a machine that has columns in it that separate chemical species by virtue of their size and molecular weight. And as they elude from that column, the gel permeation chromatograph measures the numbers of materials, the weight, puts it into the computer, and at the end of the run it provides you information about the molecular weight of the sample that was just analyzed.
Q. And read this with me for the jury, please. It says, "Gel permeation chromatography, paren, GPC, was run on Prolene sutures explanted from dogs after seven years." What does that mean?
A. They took the sutures, Prolene sutures from the dogs after seven years.
Q. And it says, "The GPC data was compared to data from a current 4 slash O Prolene suture." What does that mean?
A. That means that they took the experimental sample from the dog and they ran its molecular weight, and then they compared it to a pristine sample of Prolene that had never

been introduced to anybody, right out of the box so to speak, brand new.

Q. And why do you do that kind of analysis?

A. Called a control. In other words, if we want to know if the molecular weight of the Prolene was reduced while it was in the dog, then we need a standard or control, so we use the unused, unimplanted material as a control. This is what your molecular weight ought to be. And then you test the sample from the dog and say, well, is it the same or is it within experimental error. If it is, then nothing has happened to the molecular weight this seven years. The polymer has not degraded.

Q. So continue reading on with me. "The results indicate that there was no significant difference in molecular weight between the 4 slash O Prolene control and the seven year explants."

What does that mean to a polymer chemist?

A. That means that there was no degradation because of implantation of Prolene in the dog over a seven year period of time.

Q. Had there been degradation, what would you expect to see?

A. You would have seen a reduction in molecular weight would be one thing that you would expect to see.

Q. I want to direct your attention now to page 153 of this, of exhibit 23228. 153 is an interim report dated October 19,

1992. Do you see that?
A. Yes, I do.
Q. Tell the jury what this document is.
A. Well, this is a document that shows the physical properties of explanted materials, in particular we're interested in Prolene. It measured the physical testing, it took these samples and did tensile strength and elongation studies on them and we talked about that earlier today. And they have a chart in here which I think we'll get to a little bit later that will show you what happens to the physical properties of Prolene over the seven year period.
Q. And what were the findings -- strike that.
What different tests did they run, Dr. Thames?
A. They ran tensile strength test, which is the pull test, to determine how much force you have to put on the sample to break it. And then they determined elongation, which is how much did it extend before it finally broke. And finally they looked at modulus, which is a measure of stiffness to see if it was stiffer than when it was implanted or as stiff as when it was implanted just to get a handle on what the characteristics of stiffness was of that explanted material.
Q. Dr. Thames, what did Ethicon find after seven years of implantation happened to the tensile strength of these sutures?
A. They found that the tensile strength was reduced, as far

as my memory, it's about five PSI, slight reduction in the strength required to break the Prolene sample.

Q. What did the Ethicon scientists find with respect to elongation?

A. The sample elongated twice its original length. The first length was like 37, 38, something like that, I forget exactly the number, and finally upon explantation after seven years it was twice as elongatable.

Q. And what's the significance of the changed elongation?

A. Well, when you talk about just a very, very small reduction in strength and a very long elongation, the area under that curve of is far greater after seven years of explantation than before.

Q. Tell the jury and me what it means, area under the curve, as it relates to the ability of the suture to perform its intended function.

A. Remember we talked about the fact that the area under the curve was a measure of toughness. So what that means is that not only, not only did the Prolene explant not undergo degradation, but it improved with implantation. It became tougher. It became more elongatable with only a very minor reduction in tensile strength. So it was a tougher strand of polypropylene after seven years than it was when it was implanted in the dog.

Q. Finally, Dr. Thames, you talked about Young's modulus

test?
A. Yes, sir.
Q. Tell the jury about that, please.
A. Modulus is a test of toughness and typically slope of the curve, and since I didn't have the exact numbers I couldn't give you a curve that showed the exact shape of the modulus curve, but it's reduced somewhat, and that means the stiffness was reduced a bit during the period of time when it was being implanted. So we, we reduced stiffness, we improved elongation with very minor changes in tensile strength, and so overall the properties were enhanced during the seven year implantation.
Q. Dr. Thames, I put a slide up there that shows the data and the cover page, page 115, so the jury can see it.
A. Yes, sir.
Q. And the citation there says that "Novafil samples show a decrease in breaking strength while Prolene and PVDF showed no significant change after seven years of implantation." That refers to the breaking strength?
A. Yes, sir. Or tensile strength, the same thing. We're going to call it the same thing, okay.
Q. And is the other data up there, is that the data upon which you relied for your opinions about the Prolene becoming tougher after seven years?
A. Yes, sir.

Q. Can you explain to the jury how you read that data just so they understand?

A. If you look at the chart that says, the first segment says zero in the top line, that's at implantation. That's at the beginning. And then they measured the breaking strength or the tensile strength was 1.68, that's before it was ever implanted. And then after implantation, which is over here under the seven column, breaking strength is 1.60. So the actual strength to break it reduced by point 08 pounds or Newtons.

And then in terms of the elongation, which is the second group of numbers, the original elongation was 37 percent at zero time of implantation. After seven years it was 78 percent, 78 percent, which means that it's doubled its elasticity during the period of time that it was implanted.

And then the modulus was originally 721 and it went to 214 after seven years with a reduction of minus 70 in modulus, meaning it became more flexible, more pliable, less stiff.

Q. Can I have the next slide, please, Jamie?

Dr. Thames, I have a slide up called *Seven Year Dog Study Break Strength Versus Percent Elongation*. Can you explain that to the jury, please?

A. Yes, sir. I've taken the numbers that we just talked about in the table by the Ethicon scientists and I have plotted them in terms of breaking strength is on the vertical

column or tensile strength, elongation is on the horizontal column. The red represents the original Prolene before it was inserted into the dog, implanted; the blue represents the data that was collected from the explanted sutures after seven years of implantation in the dogs.

You'll notice the blue had a very small decline in breaking strength, as we said, point 08 pounds, but its elongation went out to 78 percent. So if I measure the area under the red and compare that area to the area under the blue, we can see that the area under the blue is twice or perhaps more than the area under the red. And when we understand that the definition of toughness is area under this stress strain curve, it's obvious then that the Prolene implant improved its toughness over the period of the seven years it was implanted in the dog.

Q. And from a polymer chemistry perspective, how can it improve?

A. It can improve by being able to be plasticized. For instance, we talked about the fact that polypropylene was a group of chains and you pull them, and as you pull them they began to stretch out and so forth, like the spaghetti that we talked about. Well, if you implant this in an animal or in human flesh, the body, there are lipids there, there are fats. Unfortunately there's probably too much on those that would be put in me because I'm a little overweight, but every human

body has a certain amount of fat in it, and those lipids are fats, they're triglycerides, we go to the doctor and have our triglycerides and our cholesterol looked at, and we know we have them in our body. Well, they can plasticize and make more pliable a molecule like Prolene.

Now, in order to understand that, I think I have to maybe use a human example. There have been times when, you know, I've worked in my shop and I've gotten grease on my hands and I've wiped it off with an organic solvent, and my hands felt dry and they felt rough. First thing I do is reach over for some hand lotion and rub it into my hands. I bet you there's been times when most of you all and I've also washed dishes at times. And when you get through washing dishes, your hands feel a little dry and a little rough, and the first thing you do is you reach over and put lanolin and lotion on them. What you're doing is putting a plasticizer on your hands so that the plasticizer can soften, move in between the molecules of your hand, your flesh, and provide elasticity and lubricity, and that's what happened here is the lubricity has been improved for the polypropylene or Prolene implant.

Q. How about a little glass of water?

A. I think I need it.

Thank you.

Q. Next slide, please, Jamie.

Jamie, next slide, please.

We already talked about this section of the report. This refers to the GPC testing molecular weight?

A. Yes, sir.

Q. Let's go to the next slide, please. What does this next slide represent?

A. Well, this next slide actually is looking at three different pieces of Prolene that were taken from the dog after the seven years and molecular weights were determined. Now, when it says current Prolene, that's the control, and we've got current Prolene in the top bar, and we've got current Prolene in the bottom bar. So we're comparing the molecular weight before implantation of Prolene to the molecular weight after seven years' implantation in the dog. And you'll notice the numbers are very close together and what you see in results below that, it says results indicate no degradation have taken place. That's in the top column. The bottom one says comparison of the seven year explants to the current Prolene indicate no molecular weight degradation.

So the molecular weights, within experimental error, are the same after seven years of implantation in the dog.

Q. Dr. Thames, what does the fact that those numbers aren't exactly the same mean?

A. Well, this is an instrument that you're using, and to get the exactly the same molecular weight actually would be suspicious, but the test is a ten percent error that you can

have and it be non -- if you have as much as ten percent, that's not a problem, that's within statistical error of the test, very close, very good.

Q. As a polymer chemist, what do these findings of molecular weight in the seven year explants tell you as compared to the controls?

A. Obviously there's been no degradation because when you combine the fact that the molecular weight hasn't changed and you've had an increase in toughness of the implant over the seven year period, that is golden that there's been no degradation of that implant after seven years.

MR. THOMAS: Your Honor, may I approach?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Thames, I've handed you what's been marked as plaintiffs' exhibit number 2026, it's already been received into evidence through Dr. Guelcher.

A. Yes, sir.

Q. The jury heard some testimony from Dr. Guelcher about this, about this document. Have you reviewed that in connection with your opinions in this case?

A. I have.

Q. And tell the jury what's going on in exhibit 2026.

A. Okay. This exhibit says IR microscopy of explanted Prolene received from Professor R. Guidoin, G-U-I-D-I-O-N. I

hope I have pronounced it appropriately.
Q. And what did those explants come from?
A. Canada, I believe.
Q. And can you tell from this document the history of those explants before they come in Ethicon's possession?
A. I have no information here. I have no idea where they came from. I don't have any idea how long they've been explanted. It says eight years and two years, but I don't know how they were treated after that, don't know where they were stored. Don't know anything about them.
Q. Why is that important to know?
A. Well, if you're going to draw a conclusion, conclusion like we're drawing here today in terms of using data, you have to have data to support your conclusion. And when you don't have any information about an explant, then you don't have much data to deal with. And, you know, we don't have any idea how they were treated, if they were put in formaldehyde or what was done to them or how long they were there. So there's just a lot of unknowns that we don't know.
Q. Jamie, do you have that, 2026?
Let's look at the first paragraph where it begins "Samples of Prolene suture carefully removed from human vascular graft explants received from Professor R. Guidoin were examined by IR microscopy as is. What are vascular graft explants?

A. I guess from the vascular part of the human body, and they are looked at as is, meaning they just took them out, didn't do any preparation for them, didn't change them in any way. And so we don't know much about them.

Q. Dr. Thames, in your experience, what happens to explants when they're removed from the body?

A. Well, when they're removed from the body, upon removal the surgeon drops them in formaldehyde or formalin in the vast majority of the cases. And when that happens, a chemical reaction begins which we need to talk about, but, so they are preserved, they are fixed as the process is called, called a fixation process.

Q. Does the potential for these explants to be stored in formalin impact the analysis of these explants?

A. To a significant degree, yes, sir.

Q. Is there any indication from this document whether or to what extent these explants were stored in formalin?

A. Well, it doesn't say, but if they're eight years old and you didn't store them in formalin, I think there would be a great deal of decomposition associated with the explants, and my feeling would be that they were stored in formalin.

Q. Now, Dr. Thames, have you studied the IR spectra which accompany this report?

A. I have.

Q. And tell the jury again what IR spectra are.

A. IR stands for infrared spectra, and the infrared spectrum of a compound is like a fingerprint to you and me. You know, you're asked when you get your driver's license and things like that to have your fingerprints made, and that's because they want to be able to identify you or me, and that's the reason there being that each individual has a unique fingerprint pattern. Well, that can be related to infrared spectroscopy. Each organic molecule has a unique infrared spectra that gives some characteristics of that particular compound.

So, but the one thing I do need to caution us about is the fact that changing instrumentation, changing the light source and so forth, will change the frequency a little bit where you'd see a particular chemical bond in a compound.

Q. Let's turn to page two of this document.

A. Yes, sir.

Q. Under conclusions. We've been through the body of it with Dr. Guelcher, I don't think the jury needs to hear this again, but under conclusions. "Number one, the amount of DLTDP is reduced in the explanted sutures. No DLTDP is observed in the surface scraped, paren, cracked regions of 83DO35. The observed DLTDP decreases with implant time.

Now, first, what is DLTDP?

A. Dilauryl thiodipropionate which is the antioxidant.

Q. Now, based on the work that you've done in your analysis

of Prolene polypropylene both in pristine samples and in explants, your training, education and experience, and your review of the spectra, the IR spectra which accompanied this report from 1987, do you agree with the finding expressed there?

A. No, sir, I do not.

Q. Can you tell the jury why?

A. Yes, sir. Infrared spectroscopy is a qualitative technique, meaning that it tells you if something is present. It doesn't tell you how much. If you want to do quantitative measurements with infrared spectroscopy, you have to be very serious about doing concentration curves and running a lot of model structures and spectra so that you can plot intensity versus concentration. You have to do that. And then once you had that plot and you knew what the concentrations of samples were and you knew what the intensity was, you could draw a plot. And then if you go to an unknown and you sample it and see what its intensity was, you can go back to that plot and estimate its concentration.

But this is a qualitative technique, it just says it's there or it's not there, and there are too many things that can interfere and override the quantity of material you may be seeing in an infrared spectra.

Q. And what is it about this statement that you disagree with?

A. Well, first of all, it's not quantitative. Secondly, it said no DLTDP is observed in the surface scraped cracked regions. Well, I wouldn't expect the DLTDP to be observed in the surface material. It's in the Prolene. And it says the observed DLTDP decreases with implant time. That's a quantitative measurement, there's no way to make that with this kind of information.

Q. The next conclusion is "No protein is observed in any spectra of the explanted sutures. What would be the significance of that finding?

A. Well, protein is present in flesh and they made no effort to clean the flesh. They took these materials and didn't clean them in any way, shape or form that I'm aware of, and so you would expect to see some protein, and I think they probably did, but they may not have recognized it.

Q. And did you review the spectra that accompanied this report and find evidence of protein?

A. Yes, sir, I think so.

Q. And could you show the jury what you mean by that?

A. Well, if you -- let me take just a second, sir.

If you look at the spectras on figure three and figure four, these are infrared spectra, figure five -- not so much figure five -- figure six.

Q. And we won't go through each of those, but tell the jury what you're seeing on these spectra that cause you to believe

you're seeing proteins.

A. I'm seeing some frequencies that are associated with proteins and -- oh, I see what you're talking about. Do I have something that I can point with, sir?

THE COURT: You can touch it with your finger and it should mark.

THE WITNESS: Okay, sir.

Right in this region right here is, you notice down here, this says 1600. You'll see protein spectra at 1660 and 1540, so then right in this region right here, you can be seeing proteins. These are your polypropylene right here. And then you also have a strong area over around the 3300 region which is where proteins absorb, right in this region right here. So that indicates to me that there's protein present. Now, there may not be much according to this, but there's some present.

Q. And how do you know as a polymer scientist what you're looking at on that spectra are proteins?

A. Well, because the chemical profession has taken a number of compounds, they run the spectra and they put them in a library, and then you run, you look at the library to see where the typical absorption frequencies are for the compound you're looking for, or you run the compound yourself, you take the protein, run the spectra and see where the frequency absorptions are. And these frequencies here and here are

where I would expect to see some protein absorption frequencies.

Q. And what do the findings of protein in the IR spectra do to the conclusions in the report that there is DLTDP reduced?

A. Well, if the proteins are there and the DLTDP is inside the Prolene, then you're going to be seeing the, mostly the proteins and not the DLTDP.

Q. The next conclusion reads "The surface scraped material from the cracked regions of 83DO35 has a melting range indicative of degraded polypropylene." Do you agree with that?

THE COURT: If you touch the corner of that, it will clear it.

BY MR. THOMAS:

Q. Do you agree with that?

A. Sir, I'm sorry.

Q. The third conclusion reads "The surface scraped material from the cracked regions of 83DO35 has a melting range indicative of degraded polypropylene." Do you agree with that?

A. Well, I don't know how that can be derived from this kind of information because it's well-known, and we've seen this from the explanted materials that, and this was of course identified in this study that there are fatty acids that are present, that there are lipids that are present, and if those

materials are present and you take a melting point, they're going to function as impurities. And any time you have an impurity present, the melting point is going to be depressed. That's just a fact of science. So if this is not pure Prolene, if there's any contaminants there, you will see a slight change in the melting point. And I don't think there's enough specific information to be able to draw that conclusion.

Q. Now, Doctor, does the data in exhibit 2026 include any molecular weight analysis?

A. No, sir.

Q. Does the data expressed in 2026 include any tensile strength analysis?

A. No, sir, it does not.

Q. Does the data expressed in 2026 include any elongation analysis?

A. No, sir.

Q. And of what significance to you as a polymer chemist is data from molecular weight, tensile strength and elongation to understand the extent to which what they are looking at in 2026 has degraded?

A. Well, it's critical because, as we pointed out this morning, that you can determine whether or not something has been degraded by virtue of whether or not its molecular weight is lowered, whether or not its physical properties have

changed, and so it's critical to know information like that if, of course, you can get that.

Q. Comparing the data that you have from the seven year dog study that the jury's already heard about and the data that you have from plaintiff's 2026, which allows you to draw any scientifically reliable conclusions?

A. The dog study certainly.

Q. Why is that?

A. Well, it's a structured study, we know exactly what was done, when it was done. We know the kind of measurements that were taken, we know how they were taken, we know how the data was accumulated, we know how it was put together and charted, it was followed with time. A structured, scientific program was affected. And we know the results of it.

Q. And what do you conclude from your review of the data you've reviewed so far as to whether Prolene polypropylene degrades in the body?

A. My opinion is it does not.

Q. Okay. Let's move on to oxidation. Let's talk about oxidation generally now. What is oxidation?

A. Oxidation is the addition of oxygen to a molecular species.

Q. Can I have the next slide, Jamie?

Why did you add this slide in your presentation?

A. Well, I just happened to have that because I took a slide

of the hood of this automobile, there was a complaint about the fact that it was degrading, and you can tell that this coating has degraded significantly, that it has oxidized, it's cracking, it's peeling and it's eroding away from the surface of the hood.

Also a specific example is this spot right here is rust, iron oxide, so we know that's oxidizing because iron FE203 is rusty color and that's what rust is. So we know because the coating broke there and the environment was able to reach the metal surface, we saw iron oxide form. And yet all around this hood we see similar results of the coating failing, it's oxidizing, it's breaking, its molecular weight is being changed.

Q. What happens to the polypropylene molecule when it oxidizes?

A. It cleaves and produces a carbonyl group.

Q. Can you show that on the board?

A. Sure can.

MR. THOMAS: May he step down, Your Honor?

THE COURT: With the same caution, yes.

THE WITNESS: I'm going to use my same --

MR. THOMAS: That one's dried out.

THE WITNESS: Okay. I'm going to use the same molecule without drawing another one, put you through that again, and show you what happens when oxygen attacks this

molecule.

Oxygen can have a structure like this with, it's O_2 is the structure of oxygen, O_2. And you see this is in a dipolar state where this bond here represents two electrons, this represents two electrons. Well, when oxygen attacks this particular polymeric system, it will extract a hydrogen from here -- and I'm going to skip one step to make this closer or easier, excuse me -- and it will perform or form a hydro peroxide. It will produce a hydro peroxide. That's an unstable molecule. That molecule will degrade, one electron will go here, one will go here, and one will go here, and the result will be -- we have CH_2. So we've taken what was molecule X, we've chopped it in two, we now have two molecules, and in the process we have produced this species which is a C double mono, which is called a carbonyl band. It's a very strong band of the infrared spectra.

Q. And what is the significance of a carbonyl band being very strong in the infrared spectra?

A. It will be very visible, it will be one of the more prominent bands in the infrared spectra.

Q. So how does that impact any FTIR test?

A. It impacts it in the fact that you would expect to see -- if this occurred, you will see a strong C double bond O spectra in the infrared spectra.

Q. And what does oxidation do to the molecular weight of

polypropylene?
A. It will reduce it. It will reduce molecular weight, which causes the sample to become more brittle and less elongatable.
Q. And how can you detect a loss of molecular weight?
A. By gel permeation chromatography.
Q. Thank you, Doctor.
We talked a little bit about the testing that you've done in these cases, in this litigation. Can I have another slide, please?
Tell the jury about the various test methods that you analyzed to analyze Prolene polypropylene?
A. Well, I've used light microscopy, number one, and I've used photo microscopy. And we've got a light microscope, photo microscopy unit over here. We've used DSC, differential scanning calorimetry studies there. We've considered gel permeation chromatography in drawing our conclusions, and we've done Fourier transform infrared spectroscopy which is here. And scanning electron microscopy which is here, of course.
Q. And what are the results of the testing that you've performed on Prolene polypropylene?
A. I have not found any degradation of Prolene.
Q. And where did you conduct these tests?
A. In our laboratories at the University of Southern

Mississippi.

Q. And were you involved in the testing that was performed?

A. Yes, sir.

Q. To your knowledge, has Dr. Guelcher performed any of the same tests on Prolene polypropylene?

A. I don't think so.

Q. Did you ask to analyze a mesh explant from Mrs. Huskey?

A. Yes.

Q. And did you analyze a mesh explant from Ms. Huskey?

A. No, sir.

Q. Why?

A. None was available.

Q. Next slide, please.

Now, for the jury, could you clean that picture up? There you go.

The jury has seen this last week. This is a slide from Dr. Guelcher's presentation, testimony, called the effect of foreign body reaction on implants. Are you familiar with this slide?

A. Yes, sir.

Q. The slide discusses polyether urethane pacemaker lead insulation. What is polyether urethane?

A. It's a completely different molecule than polypropylene and I'd be happy to show you a structure of one, if you'd like.

Q. Well, let's wait, maybe we'll get to that in a minute.
A. All right.
Q. Just tell the jury now how polyether urethane is different from polypropylene?
A. First of all, the urethane linkage, the thing that makes urethane a urethane is it has a strong carbonyl bond with a nitrogen atom attached to it, so it has a polarity associated with it unlike Prolene. In addition to that, it has a carbon oxygen carbon bond which is the ether linkage which is unlike Prolene. And those two are polar receipt materials. They have some water sensitivity to them, and they can be hydrolyzed and that means, hydrolyzed means breaking apart under the influence of water.
Q. And what's the significance of hydrolysis for degradation?
A. Well then, you reduce the molecular weight, that's the way of reducing molecular weight. If you hydrolyze a molecule, you break it in two.
Q. Dr. Guelcher used this diagram to show how polyether urethane pacemaker lead insulation would degrade in the human body. Does this same schematic apply to Prolene polypropylene in the human body?
A. No, sir.
Q. Why not?
A. First of all, we didn't have any oxidation, which is

here. Secondarily, if you don't have oxidation, we didn't have embrittlement. And we know we didn't lose any flexibility. And so it doesn't apply.

Q. What is it about the chemical structure about polyether urethane that's different from Prolene polypropylene that causes this analysis to be different?

A. Because during the process of in the body, you can have hydrolysis, you can have oxidation, and if you do that, if you get that phenomenon, it's going to embrittle your polymer and it's going to lose flexibility if the polymer is embrittled.

Q. And where in this chain does this cycle stop if it involves Prolene polypropylene?

A. Well, it never starts.

Q. Thank you.

Next slide, please.

What does this slide represent, Dr. Thames?

A. That slide represents Prolene mesh. It shows the TVT device and it shows the knitting of that. And on the bottom right-hand side we have this red line here moving over in this direction shows what an individual fiber would look like.

Q. By the way, Dr. Thames, have you ever tested a TVT-O laser-cut mesh?

A. No.

Q. Was it necessary for you to test a TVT laser-cut mesh to formulate your opinions in this case?

A. No.
Q. Why not?
A. Well, it has nothing to do with the composition of the polymer and the physical properties of the polymer.
Q. Next slide, please.
What does this slide represent?
A. This is to represent protein rich tissue or flesh which would form around and through the mesh. Now we begin to see some mesh and now the fiber is forming around it and through it, and so the mesh becomes less and less visible to the naked eye, but we can still see some particular blue strands. And it's pointed out, there's the blue strand of Prolene fiber embedded in mesh.
Q. So what's the significance of the statement protein rich tissue, what's the significance of that?
A. We know that the tissue contains protein. And remember we talked about the fact that when we take an explant out of a human, we drop it in formaldehyde, and so we have tissue now that's in the presence of formaldehyde, and the chemical reaction takes place between the tissue, the proteins, and the formaldehyde.
Q. We're getting a little ahead of ourselves here. Let's look at the Prolene fiber there. It's now a different color than it was in the prior slide. What does that Prolene fiber represent?

A. It represents a strand of material, but what we're seeing here in this case is biofilm that's formed around the Prolene fiber.

Q. Next slide, please.

Now, it says explant stored in formalin. What does that mean?

A. When the tissue is, the explant is removed from the human body, they drop it in formaldehyde to preserve it, to fix it. It's a fixation process. And that's what we see here is we have a beaker with formaldehyde and then we have the explant in the formaldehyde medium.

Q. What is the fixation process?

A. It's a chemical reaction that takes place between formaldehyde and proteins to make a high molecular weight brittle, insoluble polymer.

Q. And what medical purposes does this formalin have?

A. It's called a fixative, F-I-X-A-T-I-V-E, that's to set the material, and it's traditionally done because a histologist is going to want to slice a sample, and you want the sample to have some stability to it when a knife goes through it. So it's to hold it in place, to fix it.

Q. Next slide, please.

You spoke about a chemical reaction of protein and formaldehyde. Have you drawn a slide of that reaction?

A. I have, sir.

Q. And would you tell the jury what you have done in this slide?
A. All right. Here we see a protein molecule and we're only seeing one segment of it. It's a huge molecule. Here, and so I've used two of those because in this part of the slide and that part of the slide, two proteins, and they are coming together and they react with formaldehyde. And they react in such a way that this CH_2 right here becomes a bridge to tie these two proteins together. And so what we've done is take two large protein molecules, react them with formaldehyde, and produce even a larger, amorphous, brittle surface around the fibers, encapsulating the fibers.
Q. And how long has this chemical reaction of protein and formaldehyde been known?
A. Since 1948.
Q. Next slide, please.
Is this the study where you first found this reaction reported?
A. Well, I knew the reaction occurred, but I found the original document, yes, sir.
Q. Next slide, sir.
Now, what is the practical, what is the practical result of storing this explant in formalin?
A. If you store the explant in formalin, the protein formaldehyde polymer forms around it, as we've just shown here

in the last few slides. And when that particular explant dries out, that material becomes dry and it's brittle, and if there's any flexing at all of the explant, it will crack. And you can see that happening on this particular explanted material. You see the cracks, the transverse cracks. Right here. These cracks. But that's protein and that's formaldehyde.

Q. The brown area on top of the Prolene polypropylene is what?

A. It's a layer of protein formaldehyde polymer. The blue is the polypropylene, or Prolene I should say.

Q. Next slide, please. This is another slide from Dr. Guelcher, he referenced the 2007 Costello study. Are you familiar with that study.

A. Yes, sir.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:

Q. Let me hand you what's already been received as a learned treatise as exhibit 21468.

A. Yes, sir.

Q. And the title of the study is *Materials Characterization of Explanted Polypropylene Hernia Meshes*, correct?

A. Yes, sir.

Q. If you turn to -- could you bring up the study, please,

Jamie? Go to page two of the study. Under materials and methods, it says all 14 samples. Do you see that?

A. Yes, sir.

Q. "All 14 samples included in this study were the polypropylene components from polypropylene expanded" -- I'm not even going to try that one -- "composite hernia mesh such as Composix FX or Kugel Composix, paren, C.R. Bard, Cranston, Rhode Island, shown in figure 2." What does that tell you about the mesh that's being analyzed in this case?

A. It's not an Ethicon mesh. It was made by C.R. Bard.

Q. And why is that important to you as a polymer chemist?

A. Well, we don't know precisely what's in it. We don't know -- I don't know what the materials were that they used in the formulation. I do know exactly what was used in Ethicon. I know that the antioxidants were there and so forth, but have no idea what's here.

Q. And down at the next paragraph, under tissue removal, the first line says, "After explantation, the meshes were immersed in a ten percent V slash V formalin solution and stored at room temperature." What's the significance of that finding in the study?

A. Well, we know that when the tissue was removed, the surgeon dropped it in formaldehyde and the chemical reaction that I've just described to you between proteins and formaldehyde began. And we know then from that result that

there was a layer of protein formaldehyde fiber formed around the fibers.

Q. Okay. And what significance to you is that protein formaldehyde covering and your ability to analyze that polymer?

A. Yes. You have to remove that covering completely before you can do a scientific investigation of the Prolene fiber itself.

Q. And have you been involved in trying to remove this formaldehyde protein surface?

A. I have.

Q. And tell the jury what the process entails.

A. The process entailed reversing the reaction. In other words, if we look at that chemical reaction of the protein plus formaldehyde, when it begins to form, the polymer begins to form and it gets to be huge, become a solid, insoluble. And so if it's insoluble, it's hard for chemical reagents to get to it and destroy it. And what we found is one of the better ways to do that is because the formaldehyde reaction is reversible, is add water. Just leave it in water, heat it up for long periods of time, for days, and you increase the temperature because you want the reaction to reverse and go back. And you do that. And then every 12 hours you take the water and you remove it so that the formaldehyde that was put in the water system is removed and won't react and go forward

again, so you want to continue to reverse it.

And then at some point in time -- you continue to look at these under a microscope to see how well you're doing. And then at some point in time, you may want to use a little sodium hypochlorite to finish it off. But it takes days to do this. And you have to elevate -- well, we elevated our temperature because it reduces the time. If you increase a reaction by ten degrees centigrade it doubles the rate, so if I want to really get the stuff to come off of the fiber, I've got to heat it up and drive it to a reverse direction.

Q. Have you been able to remove all the proteins?

A. No, sir.

Q. Even after all this effort?

A. No, sir.

Q. Why is that?

A. It's because it's tenaciously bonded to the propylene fiber. Proteins have a lot of polarity and they are very good adhesives.

Q. Let's go back to the first page of 30302, please, under the abstract, down towards the bottom of the abstract. It has "Several characterization techniques were utilized" --

A. Yes, sir.

Q. -- "including scanning electron microscopy, differential scanning calorimetry, thermogravimetric analysis and compliance testing."

Is there any molecular weight analysis?

A. No, sir.

Q. Is there any tensile strength analysis?

A. No, sir.

Q. Is there any elongation analysis?

A. No, sir.

Q. Any attempt to measure the mechanical properties of that mesh?

A. None.

Q. Go to the next slide, please, Jamie.

Now go to the next one, please.

The jury also heard from Dr. Guelcher about a study done by Dr. Clavé and others in 2010 and they saw that slide with that image that you see in front of you. It suggests that the images are consistent with images from the 1992 Ethicon dog study and the suture explants. Have you reviewed the Clavé study in connection with your work in this case?

A. Yes, sir.

MR. THOMAS: Your Honor, may I approach?

THE COURT: You may.

MR. THOMAS: The Clavé study has previously been received as a learned treatise as 21457.

THE COURT: Very well.

BY MR. THOMAS:

Q. The title of the Clavé study is *Polypropylene As a*

Reinforcement in Pelvic Surgery is Not Inert, Comparative Analysis of a Hundred Explants.

What was Dr. Clavé and his other people in his study trying to do?

A. Well, they were trying to determine whether or not polypropylene did undergo degradation, and they had a hundred explants to look at, and they hypothesized that there was an oxidation going on as we described it here on the white board and that they were going to look to see if there was oxidation or if there was any loss in properties and so forth, and that's what their study focused on.

Q. And some of these explants were Ethicon products?

A. Yes, sir.

Q. Let's go to page six, please, of 30267 under discussion, first paragraph. It says, "The primary objectives of this study were to objectively observe a series of prosthetic explants and to characterize potential degradation, which may occur in vivo." And they used three methods. They used SEM, correct?

A. Correct.

Q. And that's scanning electron microscopy?

A. Yes, sir.

Q. And FTIR?

A. Yes, sir.

Q. That's the infrared analysis we talked about?

A. Yes, sir.
Q. And DSC is what?
A. Differential scanning calorimetry.
Q. Did they test molecular weight?
A. No.
Q. Did they test tensile strength?
A. No, sir.
Q. Did they test elongation?
A. No, sir.
Q. Go to the bottom right-hand corner of that same page, please, and it says, "Several hypotheses concerning the degradation of the polypropylene are described below. None of these, particularly direct oxidation, could be confirmed in this study."

What's the significance of that to you as a polymer chemist?
A. Well, he looked at a hundred explants and he wasn't able to prove that oxidation occurred, and that's oxidation that we're showing here on the white board.
Q. Let's go to page seven, please. That refers to direct oxidation of the polypropylene, the last sentence of that first paragraph says, "The FTIR analysis neither confirmed nor excluded oxidation of polypropylene in the in vivo environment." What does that tell you as a polymer chemist?
A. The FTIR analysis did not confirm oxidation in the

explanted materials that he looked at.
Q. Let's go to page eight, please. Page eight on the right side, beginning in this study, do you see that right in that paragraph? "In this study, no difference between DSC thermograms of pristine and degraded samples was found." What's the significance of that to you as a polymer chemist?
A. There was no change in the thermal history of the sample, from the hundred explanted samples that he looked at, there was no change in the thermal history, no change in the melting point essentially. There was not enough variation that he could draw any conclusion from the thermal history that he looked at those explants from.
Q. Could you find in the Clavé study any objective analytical chemist results that support the suggestion that Ethicon Prolene polypropylene degraded in vivo?
A. Absolutely none.
Q. Let's go to the next slide, please. And the next slide.
Plaintiffs also talked about the Wood article.
MR. THOMAS: May I approach, Your Honor?
THE COURT: You may.
BY MR. THOMAS:
Q. The Wood article, plaintiffs used an abstract previously received as 21925. You've seen that before?
A. Yes, sir.
Q. And have you seen the actual study by Wood?

A. I have.
Q. And were you able to determine from your review of the actual study of Wood whether that study looked at Ethicon Prolene polypropylene mesh?
A. I have, and it is not Ethicon Prolene mesh.
Q. What else did you learn from your review of the actual study in that case?
A. That they were looking at a polypropylene material that oxidized and that was shown clearly in the infrared spectra, but it was not Ethicon.
Q. Next slide, please.
The actual study shows FTIR of 1740 for oxidized polypropylene?
A. Yes, sir.
Q. And what's the significance of that to you and your work in this case?
A. Well, are we going to see the spectra?
Q. Yes, sir.
A. Could I have that?
Q. Yes. Let's go to the next slide, please, Jamie.
What are you showing the jury now in figure 3 of this FTIR spectra?
A. This is the spectra -- the blue spectra is pristine polypropylene, in other words, it has never been implanted. It's blue. And the red is the explanted polypropylene sample

that they used. And you'll notice there's a designation there of a carbonyl peak at 1740. We're talking about right here. And you'll notice, and I drew a structure of a carbonyl peak, and I mentioned to you that if it were present that the distinction would be strong and quite visible in the spectra, and that's precisely what you see here is a strong, visible peak at 1740. And the reason that we know that it's oxidized is because the blue sample, the pristine sample, has no peak at that same frequency. So it's been modified, it's been modified by oxidation.

Q. And how does the spectra which you've identified in figure three of the Wood study of a polypropylene different from Prolene compare to the FTIR spectra that you've taken of Prolene polypropylene?

A. I've never been able to identify an intensity of that kind of material at that wave length due to oxidation of the polypropylene.

Q. And what does the your inability to define that peak found in the Wood article tell you about Prolene polypropylene?

A. It didn't oxidize.

Q. Now, Dr. Thames, did you analyze the benchtop testing conducted by Ethicon concerning its laser-cut mesh and mechanical-cut mesh?

A. Yes, sir, I did.

Q. And tell the jury what benchtop testing is.
A. Well, it's in a laboratory. You go into a laboratory and you have a work bench and you devise techniques to determine what it is you want to determine. For instance, if you want to determine molecular weight of a GPC sitting on the benchtop, so that's where experimentation was done to make the studies with laser-cut versus mechanical cut mesh.
Q. And did you analyze the kinds of testing that Ethicon did in the machine-cut versus mechanical cut comparison?
A. Yes, I did.
Q. And would you tell the jury what elongation testing is, please?
A. Elongation testing, if we remember, we were talking about the strands where you take the sample and you stretch it from its original length and you see how far you can stretch it. That's the elongation test.
Q. And what is the, what is flexural rigidity?
A. Flexural rigidity in this case is they want to know how rigid the samples are, and what they do to evaluate that is an ASTM test, American Society of Testing Materials type test, where they take a piece of, I'll just use an example here of a mesh, and they move it out over the table. And you'll see how the paper begins to bend? And there's some point at which the test will be over when it goes at a certain angle. And then the key is if it reaches that angle at a very short distance

here, it's stiff. If it takes it a long, you have to go out a long way before the mesh bends, then it's not so stiff, it's not so rigid. And that's the way the evaluations were determined.

Q. And what do these benchtop tests tell the company about the comparison between the machine-cut and the laser-cut mesh?

A. They're essentially the same.

Q. And just so the jury understands, what does it mean to machine-cut a mesh as opposed to mechanically cut a mesh?

A. Well, this is an example. We all know what a paper cutter looks like, one where you can cut a piece of paper, that would be a mechanical cut, or a pair of scissors would mechanically cut it. Laser-cut is where enough energy is put into a cutting edge that you can actually produce heat, vibrating the sample, and you melt the sample rather than physically cutting it. So you will melt it and it's cut by melting and not by physical cutting.

MR. THOMAS: Your Honor, may I approach?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Thames, I'm handing you what's been marked as defendants' exhibit 22463. It's an article by Dietz and others concerning the mechanical properties of implanted materials used in incontinence surgery. Did you review this study in connection with your opinions in this case?

A. I did.
Q. And did you rely on it in the formulation of your opinions in this case?
A. Yes, sir.
MR. THOMAS: Your Honor, I'd offer 22463 as a learned treatise.
MR. KUNTZ: No objection, Your Honor.
(Defendants' Exhibit 22463 received in evidence.)
BY MR. THOMAS:
Q. Could you bring that up, please?
What are they doing in the Dietz study?
A. They're looking at a variety of different materials that are used for implantation; in this particular case, nylon, IBS, TVT, Gore-Tex Soft, Gore-Tex Micromesh, Mersilene and Prolene. They're evaluating a variety of different materials that are used.
Q. What tests are they running?
A. They're running a mean stiffness test to determine the stiffness as we've described here, how stiff those meshes are going to be.
Q. Jamie, can we bring up table one, please? Could you blow up that, please?
And Dr. Thames, what does table one tell us?
A. It tells us if you look at Prolene, TVT -- excuse me, let's go TVT, you'll see that it has the lowest mean stiffness

value and the second most lowest is the Prolene itself. TVT is of the device, and Prolene is the material, the material, Prolene. So it's very low, it shows very low stiffness in relationship to the other materials that are used in that particular work.

Q. Let's go to the conclusions on the next page, please. Beginning as demonstrated in this study. It says, "As demonstrated in this study, the TVT shows unusual biomechanical properties when tested against other routinely used implant materials."

A. Yes, sir.

Q. "Of the tested permanent mesh products, it has by far the lowest initial stiffness, i.e., it exhibits less resistance to defamation at forces below the elastic limit. The elastic limit is only reached at an elongation of almost 50 percent of its initial length, although at relatively low forces. The fracture point is reached at very high elongation and on exertion of a relatively high force."

Of what significance is that to you and your opinions in this case?

A. Well, it shows that it's a very good material, that it's not stiff, it's not, we know it not to be brittle, and it's one of the best materials on the market today according to this work, if not the best.

MR. THOMAS: Your Honor, may I approach?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Thames, I've handed you what's been marked as defendant exhibits 21349.

A. Yes, sir.

Q. It's a memoranda from Gene Kammerer to Marty Weisberg and David Robinson dated March 6, 2006. Did you review this document and utilize it in your opinions in this case?

A. I did.

MR. THOMAS: Your Honor, I offer into evidence defendants' exhibit 21349.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(Defendants' Exhibit 21349 received in evidence.)

BY MR. THOMAS:

Q. Tell the jury what's going on in this exhibit, Dr. Thames, 21349.

A. Well, Ethicon did quite a bit of work to confirm that laser cutting was an appropriate way to prepare the mesh samples. They did design experiment work, they determined the best power out for the laser, they determined the length of time that's best for cutting it, and then they compared that to the mechanical cut, mechanical cut meshes, and those analyses are somewhat included here in this particular report, Mr. Thomas.

Q. And under conclusion?
A. Yes, sir.
Q. Can we scroll down to that, please? And blow-up the first paragraph.

"The elongation analysis determined that each of the two methods of cutting produces meshes which have statistically the same properties of elongation within the first five percent elongation of the mesh. This data is contained in the report, *Performance Evaluation of TVT Prolene Blue Mesh*."

What's the significance of that conclusion?

A. Well, they're essentially the same, mechanical-cut and laser-cut, up to five percent elongation of the mesh.
Q. And what is the significance of the five percent figure?
A. Well, that's the number that you would expect to not exceed in the human body with a cough or a strong reaction.
Q. And is that based upon findings from another study that's cited in this report?
A. Yes, it is; the Lin study.
Q. And if you go to the next page, please, in the first full paragraph, if we look at, 21349 looks at elongation tests, correct?
A. Yes, sir.
Q. And did Ethicon look at the actual difference in distance in elongation from a machine-cut and a laser-cut mesh?

A. Yes, they did.
Q. And at one Newton force -- what's a Newton?
A. A hundred pounds. Per cubic grams, excuse me, grams.
Q. At one Newton force, what is the difference in elongation between machine-cut mesh and laser-cut mesh?
A. Point 011 inches, one hundredth of an inch.
Q. And at the bottom of the conclusion, it is evident. Would you blow that up, please? I'm sorry. All the way down at the bottom, please.
"It is evident the elongation profile, paren, curve, of laser-cut mesh is equivalent to that of mechanically-cut mesh within the critical physiological range as defined by the maximum average force of 0.5 Newtons identified by A.T. Long Lin in the referenced study from March 2005."
A. Yes, sir.
Q. What's the significance of that to your opinions in this case?
A. Well, this gentleman has established a maximum average force and we know that the elongation goes with that force over a five percent elongation range is no difference at all in the two kinds of cutting techniques.
MR. THOMAS: Your Honor, may I approach?
THE COURT: You may.
BY MR. THOMAS:
Q. Dr. Thames, I've handed you what's been marked as

defendant exhibits 21229. It's a document dated May 5, 2005 titled *Performance Evaluation of TVT, Mechanical-Cut Versus Laser-Cut*.

Did you utilize that in the formation of your opinions in this case?

A. I did.

MR. THOMAS: Your Honor, I offer into evidence defendants' exhibit 21229.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(Defendants' Exhibit 21229 received in evidence.)

BY MR. THOMAS:

Q. What is flexural rigidity?

A. We talked about this where we talked about the fact that if you flex it, whether or not the sample is going to be rigid or not, whether it's going to be pliable and move easily, then it's not rigid. And that's talked about here in table number one, for instance.

Q. Tell the jury, please, what Ethicon did to test flexural rigidity of the machine-cut as compared to the laser-cut mesh?

A. Well, they did the same sort of techniques that I described earlier where they used an ASTM technique to determine the rigidity, and that's an ASTM 1388 stiffness of fabrics, rigidity of fabrics.

Q. And if you go to page three of this exhibit, they report

their conclusions.
A. Yes, sir.
Q. The fourth bullet point down on flexural rigidity, it reads "Flexural rigidity was higher for the mechanical-cut one-by-eight inch versus the laser-cut one-by-eight inch in the machine direction."
A. Yes, sir.
Q. What does it mean in the machine direction?
A. Machine direction is the direction that cutting was done to produce the Prolene mesh, and that's the direction that is used of the manufacturer, and that's the direction that is important for supporting the human organs that they're to support.
Q. And the next bullet point reads "Flexural rigidity was similar between mechanical-cut mesh and laser-cut mesh, 0.433 one inch by eight inch samples in the machine direction." And what's the significance of that finding?
A. Well, first of all, they're very similar. It's basically not much difference at all in the two of them, and that's in the machine direction just like we talked about previously.
Q. Are the elongation tests and the flexural rigidity tests appropriate tests to evaluate the mechanical characteristics of machine-cut and laser-cut mesh?
A. Yes, sir.
MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Thames, I've handed you what's been marked as defendants' exhibit 1350, a clinical expert report dated March 7, 2006.

A. Yes, sir.

Q. Have you seen that document before?

A. I have, yes, sir.

Q. Did you use that with the formulation of your opinions in this case?

A. I did.

Q. And this is the laser-cut mesh for Gynecare TVT -- I'm sorry. This is the clinical expert report *Laser-Cut Mesh For Gynecare TVT Support For Incontinence*?

A. Yes, sir.

Q. And Gynecare TVT-O obturator system?

A. Yes, sir.

MR. THOMAS: Your Honor, I move into evidence defendant exhibits 21350.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(Defendants' Exhibit 21350 received in evidence.)

BY MR. THOMAS:

Q. Dr. Thames, this document is signed by Martin Weisberg, M.D., senior medical director of Ethicon, Inc., and David

Robinson, medical director of Ethicon Women's Health and Urology on March 7, 2006, correct?

A. Yes, sir.

Q. Let's go to page three. Under preclinical evidence, first paragraph. "In order to assure that changing from mechanically-cut mesh to laser-cut mesh would not result in an adverse clinical impact, preclinical investigations were undertaken. These investigations were performed to ensure that there were no clinically significant changes in the properties of the mesh resulting from process modifications. These studies compared elongation, flexural rigidity, and particle loss properties of laser-cut versus mechanically-cut Prolene mesh." Correct?

A. Yes, sir.

Q. Now, continuing on down, the clinical expert report reports on the findings of the work that was done. Is this the studies that you've already just talked about?

A. Yes, sir.

Q. And the paragraph continues, "The elongation analysis determined that each of the two methods of cutting produces mesh that have statistically the same properties of elongation within approximately the first four to five percent elongation of the mesh, based on the selected cutting parameters." Do you agree with that finding?

A. Yes, I do.

Q. And likewise, the next paragraph discusses the flexural rigidity findings, correct?
A. That's correct, sir.
Q. And in this paragraph the clinical expert report states that flexural rigidity was slightly higher for the mechanically-cut mesh versus the machine-cut mesh. What does that mean?
A. That means that the mechanical-cut mesh is going to be a bit more rigid than the laser-cut mesh.
Q. "The rigidity of the mechanically-cut and the laser-cut for the samples in the cross direction was similar. This should result in no clinical differences in this respect."
Is that what you just discussed a few minutes ago?
A. Yes, sir.
Q. Dr. Thames, do you have an opinion to a reasonable degree of certainty as to whether the Prolene mesh in the Ethicon TVT-O device degrades in the human body?
A. I do.
Q. And what is that opinion?
A. It does not degrade.
Q. Do you have an opinion within a reasonable degree of certainty as to whether the Prolene mesh in the Ethicon TVT-O device oxidizes in the human body?
A. I do.
Q. And what is that opinion?

A. It does not oxidize.
Q. And do you have an opinion to a reasonable degree of certainty as to whether the Prolene mesh in the Ethicon TVT-O performs as expected from a polymer chemistry perspective?
A. I do.
Q. And what is that opinion?
A. It performs as expected.
Q. Do you have an opinion to a reasonable degree of certainty as to whether using a laser to cut the Prolene mesh into the Ethicon TVT-O device adversely affects the mechanical properties of that mesh?
A. I do.
Q. And what is that opinion?
A. It does not adversely affect its properties.

MR. THOMAS: Your Honor, may I have a moment, please?

THE COURT: Yes.

MR. THOMAS: That's all the questions I have. Thank you, Dr. Thames.

THE COURT: All right. Cross examine.

MR. KUNTZ: Yes, Your Honor. Can we approach real quick?

THE COURT: Sure.

(The following occurred at sidebar.)

THE COURT: All right, sir.

MR. KUNTZ: This is an issue we have about

cross-examining. I was going to impeach him with a document after he got up and said over and over his name's on the building at Southern Mississippi, that his legacy is there. The truth is, Your Honor, there's a lot of issues related to his legacy. This is an actual official document from the Southern Mississippi senate that shows that the faculty, 400 members at a 93 percent voted no confidence against him.

There's a lot of inflammatory stuff in this document. There's a whole another box about sexual misconduct. I'm not getting into any of that. I'm not getting into any of the issues about him spying on students' emails. And you can read the whole document yourself, Your Honor. This is from the Southern Mississippi, USM faculty senate, an official document.

He just got up here and said his name's on the building, he's trying to say that that's his legacy at the university. I'm going to simply ask him one question, you had a vote of no confidence against you by 93 percent of a 400 person faculty. That's it. The fact that his name's on the building doesn't -- they're trying to establish that's his legacy and it's not. You can pay to have your name on the building, it doesn't reflect his legacy as evidenced there by the senate and the faculty.

MR. THOMAS: Your Honor, Dr. Thames was, in fact, president of the University of Southern Mississippi. I never

told the jury that. He never told the jury that. The fact that he was president of the University of Southern Mississippi has nothing to do with the opinions he offers in this case as a polymer chemist. The fact that he is a polymer chemist qualified as he has been, we can't get into the sideshow of what happens when you're president of a university. I think that we could be talking about all kinds of issues that have nothing to do with his opinions in this case.

MR. KUNTZ: Judge, one, it's a cross of an expert. Two, there's a lot of stuff I'm not going to get into. But to say that his legacy is his name on the building and to prop him up like that opens it up to what his real legacy was at the university. The fact that his name on the building, Bernie Madoff still has his name on buildings in New York. My point is you can pay for that. And to prop him up like that, I think it's a fair question to ask you had a vote of no confidence against you. If he disagrees, then I bring this in.

THE COURT: Let me ask you this: When was his name placed upon the building, before or after he was president?

MR. KUNTZ: I don't know the answer to that question.

MR. THOMAS: Before.

THE COURT: The vote of no confidence was of him as president?

MR. KUNTZ: Yes.

THE COURT: It seems to me to be attenuated when only reference he made in direct that would make it relevant is the legacy remark, which I don't recall, but I take your point. Let me just finish. And it seems to me it would be highly prejudicial to show a vote of no confidence in him as president when that was not brought up nor was his performance as president in any way implicated in his direct examination.

Now, if there's something in here that goes to his performance as a professor of polymer chemistry as head of the building or what's the name of it?

MR. KUNTZ: Shelby Thames Polymer Science Building.

THE COURT: Yes. If there's anything related to that in here. I'm ruling that his performance as president of the university and impeachment regarding that is inappropriate.

MR. KUNTZ: Okay.

THE COURT: Do you have anything in here that goes to his chemistry, his relationship with the chemistry?

MR. KUNTZ: I'll look through my other stuff, but --

THE COURT: Do you want a minute or to two?

MR. KUNTZ: No. I'll look at lunch.

(Sidebar concluded.)

MR. KUNTZ: May it please the court.

THE COURT: Yes, sir. You may inquire.

(CROSS EXAMINATION OF SHELBY THAMES BY MR. KUNTZ:)

Q. Dr. Thames, good afternoon, or good morning.
A. Hello, sir.
Q. We just met the other day for the first time, correct?
A. Yes, sir.
Q. You're not a medical doctor?
A. No, I'm not.
Q. And you're not a biomedical engineer?
A. No, sir.
Q. And you're here testifying at the request of Mrs. Jones' law firm, Butler Snow, correct?
A. That's correct.
Q. And you have worked with Ms. Jones and her law firm on several occasions, haven't you?
A. Yes, sir.
Q. In fact, you have been providing expert testimony for Butler Snow, her firm, for over 20 years, haven't you?
A. Well, I wouldn't go so far as to say that.
Q. You've been expert --
A. I have worked with them before, but not over a 20-year span, sir.
Q. You haven't worked with her firm since 1996, is that your testimony?
A. I don't remember the exact dates, but I did some testimony work for them in the breast implant litigation.
Q. So you've been working with them for a long time?

A. Well, not continuously, sir, but yes.
Q. And you've given approximately 50 depositions as an expert witness?
A. That's an estimate, yes, sir.
Q. And 99 percent of those times have been for corporate defendants, correct?
A. That's correct, sir.
Q. Ninety-nine percent of the time that that's been for big industry?
A. Well, not necessarily big industries, but --
Q. Chemical companies, medical companies, oil companies?
A. Yes, I'd say that's probably right.
Q. And so far in this case you've billed $200,000 worth of --

MR. THOMAS: Objection, Your Honor. May we approach?

THE COURT: Sure.

(The following occurred at sidebar.)

THE COURT: All right.

MR. THOMAS: Your Honor, he has billed $200,000 in this litigation, but he has not billed $200,000 in this case, and we're bringing in the other cases which is where I think the court has cautioned us about throughout the litigation and I think that's inappropriate. In order for me to explain it he'd have to talk about all other cases he worked on.

MR. KUNTZ: Your Honor, he talked about all explanted

meshes and the work he's done in the other cases and for that, part of the testing for that he has billed 200,000.

THE COURT: I'm trying to figure out without knowing what percentage is fairly attributable to this case, do we have any idea?

MR. THOMAS: Yes, Your Honor.

MR. KUNTZ: He talked about all of the explanted mesh, that's part of his opinion.

THE COURT: I know he did. I know he did.

MR. THOMAS: He at, as of the time of his deposition it was about $19,000 for the Huskey and Edwards cases.

THE COURT: Was that before he examined all the meshes?

MR. THOMAS: That was after because the Lewis case was where he examined all the meshes with Dr. Jordi. Same reason we didn't go into, remember we were not able to cross examine Dr. Jordi for the million dollars that he received because it was on all these other meshes.

MR. KUNTZ: Your Honor, he just talked about all the work he did several times. I've looked at all these explanted mesh, I mean that's what he billed $200,000 for. It's fair game. He talked about all the work he's done and all the meshes he examined.

THE COURT: I've got a direct contradiction between what counsel is saying. As I understand Mr. Thomas, he's

saying that the 200,000 or that the $19,000 figure included the examination of the meshes and you're saying --

MR. THOMAS: If you understood that, Your Honor, then I misspoke because he was first retained in the Lewis case and that's when Dr. Jordi did all of his work.

THE COURT: Question. How much money was involved in all of the examination of the meshes which he talked about? How much did you spend on that?

MR. THOMAS: It's difficult to break that down from the depositions and the preparation he did in reports for the other cases. What Mr. Kuntz has asked him about is the total that he's been paid for all of the litigation. That's the problem that I have with it.

THE COURT: Is it difficult, it is a difficult circumstance, I can recall in the first Bard trial, you know, hundreds of thousands of dollars if not millions came in without objection and I was wondering about it at the time.

I don't think it's fair to bring it all in. I do think it's fair to say based on what you've represented and what I heard him say about examining the meshes and so forth, that he's been paid well into the six figure range.

MR. KUNTZ: Right. Here's my problem. I wasn't going to ask him until on direct he started getting into all the materials and --

THE COURT: Will you settle for well into six figure

range?

MR. KUNTZ: Yes.

THE COURT: Go do it.

(Sidebar concluded.)

THE COURT: All right, sir. You may inquire.

BY MR. KUNTZ:

Q. Dr. Thames, for your work in this litigation you have earned into the six figures, correct?

A. Probably.

Q. And in just preparation for your deposition in this case that you gave you charged $18,000, correct?

A. No, sir.

Q. You didn't earn $18,000 in 48 hours preparing for your deposition in this case?

A. Oh, you're talking about since I've been here?

Q. Yes.

A. I haven't added it up, sir. It's $375 an hour, just like I said.

Q. You talked a lot about polypropylene on your direct, remember that?

A. I do.

Q. This is the first case you've ever testified as an expert regarding polypropylene material that was implanted in the human body?

MR. THOMAS: Your Honor, I'm sorry. I have to

approach again.

THE COURT: All right.

(The following occurred at sidebar.)

THE COURT: Yes, sir.

MR. THOMAS: Your Honor, Dr. Thames testified in Texas, in a TVT-O case down in Texas, and the question was you haven't, it calls for him to answer that question.

MR. KUNTZ: I'll rephrase it. Prior to the Ethicon litigation is the only way I can rephrase it.

THE COURT: Let me hear it.

MR. KUNTZ: Well, if he doesn't want to bring other cases into it which was the previous objection, then I can say prior to this Ethicon litigation you've never testified as an expert about polypropylene planted in a human body.

MR. THOMAS: I have no problem with that.

THE COURT: Okay.

(Sidebar concluded.)

THE COURT: Listen to the question carefully and I think you can answer it yes or no.

BY MR. KUNTZ:

Q. Prior to the Ethicon litigation regarding polypropylene products in the pelvic floor you have never testified as an expert regarding polypropylene material implanted in the human body, correct?

A. Yes.

Q. And prior to your involvement in the Ethicon mesh litigation you've never analyzed explanted polypropylene materials?
A. Correct.
Q. And prior to being hired by defendant Ethicon in this litigation you've never evaluated or tested the durability of polypropylene mesh?
A. Correct.
Q. And prior to this case you've never studied the potential for degradation for polypropylene mesh and you've never performed any testing or analysis of the polypropylene mesh device, true?
A. No, not true.
Q. Prior to the time Ethicon hired you you've never studied a polypropylene medical device, correct?
A. Oh, medical device. I have studied polypropylene, but not as a medical device.
Q. Never studied polypropylene as a medical device that's permanently implanted in a person's body?
A. That's correct, sir.
Q. Prior to being hired by defendant Ethicon for the pelvic mesh litigation you've never tested polypropylene for degradation, correct?
A. That's correct.
Q. In fact, prior to this litigation you've never performed

any testing on polypropylene?
A. I can't say that's true. I've done a lot of testing and I can't say that I've never done any, but I've done very little, if any, at all.
Q. So very little before hired by Ethicon, testing on polypropylene?
A. Testing, that's correct.
Q. And you've never published an article, out of the 169 that you were shown on direct, about polypropylene degradation?
A. Correct.
Q. And you've never done any study comparing TVT-O laser-cut mesh to mechanical-cut mesh, correct?
A. Other than this study, yes, sir.
Q. Well, in fact, you've never analyzed TVT-O laser-cut mesh in this case, correct?
A. That's correct, yes.
Q. So you've never done a study between mechanical-cut and laser-cut mesh, isn't that true, Doctor?
A. That's correct.
Q. In fact, you've never even held a TVT-O laser-cut device in your hand, have you?
A. That's correct.
MR. KUNTZ: Probably a good place to stop, Your Honor.

THE COURT: How much more you got?

MR. KUNTZ: Probably 20 minutes.

THE COURT: All right. Twenty minutes is longer than I would, yes. We'll take our lunch break. Hour and ten minutes, we'll start again at ten after 1:00.

During the lunch break do not discuss the case among yourselves, permit anyone to discuss it with you or in your presence. Do not read anything about this case. Do not listen to anything. Do not watch anything. Do not use any social media. Don't use a computer, don't do any research. Have a nice lunch, I'll see you at ten after 1:00.

You may step down, sir.

Court's in recess.

(The Jury left the courtroom at 12:04 p.m.)

(A recess was taken at 12:04 p.m.)

(**SHELBY F. THAMES, Ph.D.**, HAVING BEEN PREVIOUSLY SWORN, TESTIFIED AS FOLLOWS:)

(The witness resumed the stand.)

(The jury entered the courtroom at 1:10 p.m.)

THE COURT: Please be seated.

You may proceed.

(CONTINUED CROSS EXAMINATION OF SHELBY F. THAMES BY MR. KUNTZ:)

Q. Dr. Thames, when we left off, you've never done any type of study on the TVT-O laser-cut mesh, correct?

A. That's correct.
Q. I want to talk to you about a few articles you discussed on direct examination. Okay?
MR. KUNTZ: Evan, if we could pull up what's already been admitted Plaintiffs' Exhibit 14114.
BY MR. KUNTZ:
Q. And this is the Céline Mary article?
A. Yes, sir.
Q. About halfway down, after one and two years -- do you see that statement: "After one and two years, in vivo," meaning in the body, "the explanted polypropylene sutures showed visual evidence of surface stress cracking." Correct?
A. That's what it says, sir.
Q. Okay. And this article states that polypropylene degrades, correct?
A. Would you show me that?
MR. KUNTZ: If you turn to the back, Page 205, Evan.
BY MR. KUNTZ:
Q. You reviewed this article closely in forming your opinions you discussed on direct, correct?
A. I reviewed the article, correct.
Q. And under "Conclusion," if we go to "visual evidence."
"Visual evidence of surface degradation was observed after one and two years for the polypropylene but not the PVDF sutures." Correct?

A. That's what it suggests.
Q. Okay. So this article suggests that degradation occurred in polypropylene sutures.
A. That's what they say.
Q. Okay. And the PVDF sutures where they don't see any degradation is a completely different product than the Prolene mesh, correct?
A. That's correct.
Q. Okay. And so you disagree with Céline Mary's article that degradation occurs?
A. I do.
Q. Okay. And let me ask you, Dr. Thames, this is a peer-reviewed article, correct?
MR. KUNTZ: If you can pull back up the beginning.
(The document was published to the jury.)
BY MR. KUNTZ:
Q. That's the conclusions of all of these authors in this article that are all listed below the title that degradation occurs in polypropylene, correct?
A. I would gather so.
Q. Okay. And this is a peer-reviewed article, isn't it?
A. I would think so.
Q. So that means other people outside the authors have reviewed this to its correctness and authenticity, correct? That's what happens in the peer-review process?

A. That's correct, they have reviewed the article and -- and, yes --

Q. And so you disagree with not -- all those authors and you disagree with all the people that peer reviewed it, correct?

MR. THOMAS: Your Honor, asked and answered.

THE COURT: Overruled.

THE WITNESS: I disagree with the analysis that -- the conclusions that they've arrived at for the reasons that I've explained today.

BY MR. KUNTZ:

Q. And you've never studied polypropylene mesh until this litigation, correct?

A. That's correct.

MR. KUNTZ: Okay. Please pull up Plaintiffs' Exhibit 14115.

(The document was published to the jury.)

THE COURT: Would you scoot up a little bit closer to the mic?

THE WITNESS: Yes, sir.

BY MR. KUNTZ:

Q. This is an article we discussed on the direct, the Clavé article. Do you remember that one?

A. I do.

Q. And, again, this is several authors, and this is 2009, and the International Urogynecological Association, correct?

A. That's correct.
Q. Okay. And in this article, they also found that degradation might occur in polypropylene, correct?
A. They found it might but that they could not prove it, sir.
Q. But they -- they say in their conclusion -- let's pull up the conclusion -- "This is the first study to evaluate synthetic implants used in the vaginal approach for pelvic floor reinforcement." Correct?
A. That's what it says, yes, sir.
Q. Okay. And if you go back over to the left side, under "Abstract," they say, "While previously recognized as" -- "as inert" -- correct, do you see that?
A. I do.
Q. -- "polypropylene is associated with high complication rates." Do you see that?
A. That's what they say.
Q. Okay. And you believe it is inert, correct?
A. No. Nothing is inert. I do not believe, under the conditions that it's used in the body, that it degrades or oxidizes.
Q. You're not an expert in dealing with medical implants in the body, are you?
A. I'm an expert in polymer science and chemistry.
Q. But you've never studied, never worked with, and your

expertise is not how medical implants react in the body, correct?

A. I understand the chemistry, whether it's in the body or out of the body.

Q. But you don't understand, as a biomedical engineer or as an expert, how it acts in the body, correct?

A. Well, an engineer is different from a chemist. And I am a polymer scientist and I look at things differently. I look at the data that's arrived at, that I can look at and make a conclusion, and every piece of data that I considered to be validly taken and presented does not show degradation, sir.

Q. Okay. So you don't -- you disagree with this article that even raises the concern of degradation, correct?

A. No, I don't disagree with the fact that they are studying it to determine whether it can degrade or not, but in this article, he -- in every instance he tested, he said, "I cannot prove that it degrades." We went over that in the direct examination.

Q. Let's pull up Plaintiffs' Exhibit 4116. This is the Dr. Wood -- or the A.J. Wood study you talked about on direct.

MR. KUNTZ: If you turn to the back page, Evan, starting with the first page. It's Plaintiffs' Exhibit 14166R.

(The document was published to the jury.)

BY MR. KUNTZ:

Q. And this is another article --

MR. THOMAS: Excuse me, counsel. I don't think this is the same one that's in evidence.

MR. KUNTZ: Okay.

MR. THOMAS: I think we need to approach on this.

THE COURT: All right.

(The following occurred at sidebar.)

THE COURT: Mr. Thomas?

MR. THOMAS: The one that I had was the abstract. And the abstract was what I understood had been admitted, not the study. The reason why I approach here is because there is a paragraph in there about the FDA that I'm sure you do not want to publish to the jury.

MR. KUNTZ: That's why it's redacted.

MR. THOMAS: I just want to make sure.

THE COURT: Okay. You may proceed.

MR. KUNTZ: It's redacted.

MR. THOMAS: Is it the same exhibit?

MR. KUNTZ: No, it's not. This is the actual published study, not the abstract.

MR. FAES: That's the one you referred to, I believe, in your direct examination.

MR. THOMAS: That's fine.

THE COURT: That's all right. Go ahead.

(Sidebar concluded.)

THE COURT: You may proceed.

(The document was published to the jury.)

MR. KUNTZ: May I approach, Your Honor?

THE COURT: You may.

THE WITNESS: Thank you.

BY MR. KUNTZ:

Q. Dr. Thames, have you seen that article before?

A. Yes, sir.

Q. Okay. And you would agree with Dr. Wood's article and conclusion that mesh degrades -- you disagree with the conclusions in this article, correct?

A. This is not Ethicon's mesh, sir.

Q. It's polypropylene mesh, correct?

A. Well, it's polypropylene, but it's not Prolene.

Q. Do you disagree with Dr. Wood who found that degradation occurs in polypropylene mesh in this article?

A. No, sir.

Q. Okay. You do not disagree with her?

A. Polypropylene mesh degrades in this article, yes, sir.

Q. Okay. So polypropylene mesh degrades, but Ethicon's mesh does not degrade?

A. That's correct.

Q. That's your position here today?

A. That's the chemistry, sir.

Q. Okay. So there's something unique about Ethicon's

Prolene mesh that doesn't degrade, while all other polypropylene mesh degrades?

A. There is, sir.

Q. Okay.

MR. KUNTZ: May I approach, Your Honor?

THE COURT: You may.

BY MR. KUNTZ:

Q. I hand you what's been marked Plaintiffs' Exhibit 893.

THE COURT: Say that again.

MR. KUNTZ: Plaintiffs' Exhibit 893.

BY MR. KUNTZ:

Q. Have you ever seen this document before, Dr. Thames?

A. I don't know that I have, sir. Let me look just a moment, please.

Q. I'll represent to you that this document's not in your reliance materials in this case.

A. You said it's not?

Q. It is not.

A. Well, then I haven't seen it, sir. It doesn't look familiar to me.

Q. So Ethicon's attorneys didn't give you this document to review in forming your expert opinions?

A. (Pause.)

I don't remember seeing this document.

Q. Okay. Do you understand -- let's look at the first page

of this document. What's the title of it?
A. It says, "Investigating mesh erosion in pelvic floor repair."
Q. Okay. It's dated when?
A. 22nd of June, 2011.
Q. Okay. Did you understand that this is an Ethicon internal document related to a consulting group they hired to review their meshes?
A. Now, I've seen a document from PA Consulting. I didn't recognize it as this. And I may have seen this, but I've seen PA Consulting documents.
Q. Okay.
A. I'm sorry. Go ahead and ask your question.
MR. KUNTZ: I'll ask you to turn to Page -- this is already in evidence, so if we can bring it up, it's the first page.
(The document was published to the jury.)
BY MR. KUNTZ:
Q. "Investigating mesh erosion in pelvic floor repair, June 22nd, 2011." Do you see that?
A. I do, sir.
Q. And if you turn to Page 5, and this is all the groups of people and scientists and Ethicon employees that the PA Consultants met with. Do you see that?
A. I see the page, what it says, yes, sir.

Q. And that's 12 people that the outside consultants interviewed about Ethicon meshes, correct? Do you understand that?
A. Looks like that's the case.
Q. And if we turn to Page 30 -- I'm sorry -- Page 35.
A. 35?
Q. Yes. The consultants that reviewed Ethicon's documents reviewed their meshes -- the title of this slide was, "Polypropylene can suffer from degradation following implant," correct?
A. That's what the title says, yes, sir.
Q. And you disagree with that, correct?
A. Yes, sir, for the reasons I stated.
Q. Okay. And it states below that, "Polypropylene has a long history of use, but it is subject to degradation, a process which initiates after a few days postimplantation in the animal studies."
A. That's what it says.
Q. Okay. And you disagree with that, don't you?
A. I certainly do.
Q. Okay. And, in fact, they talk about degradation of -- down three bullet points, "Degradation of polypropylene is also reported in the eye, where sutures were used to implant intraocular lenses," correct?
A. That's what it says.

Q. At least they believe that sutures degrade as well, correct?
A. The eye is different from inside the body, sir.
Q. And you've never studied meshes in the pelvic floor, have you, Dr. Thames?
A. What do you mean by meshes, sir?
Q. Mesh.
A. I have studied explant --
Q. You're not an expert in how mesh reacts in the pelvic floor, are you?
A. I'm not a medical doctor. I'm not a pathologist. I'm a polymer scientist and chemist.
Q. Right. And you never, until you got involved in this litigation, ever looked at meshes in the pelvic floor or how meshes react with the pelvic floor, correct?
A. That is correct.
Q. I'm going to hand you what has been marked -- and you understand this PA Consulting document was a company hired by Ethicon to review their meshes. Do you understand that?
A. I do.
Q. Okay. And you weren't shown this document before you issued your expert report in this case, were you?
A. Well, I'm not real sure about that. I think that the front page here didn't look familiar to me, but I did see a document provided to me by PA Consultants and this may be it.

Q. It wasn't on your reliance list in this case, was it?
A. Well, the PA Consulting document that I saw should have been, because I've had it for some time, sir.
Q. Did you see it for the first time this weekend?
A. No, sir.
MR. KUNTZ: May I approach, Your Honor?
THE COURT: You may.
BY MR. KUNTZ:
Q. I'm going to hand you what's been marked Exhibit 14462.
A. Thank you.
Q. Have you ever seen this document before, Dr. Thames?
A. I need to look at it a little bit first.
MR. THOMAS: Your Honor, may we approach?
THE COURT: Yes.
(The following occurred at sidebar.)
THE COURT: Mr. Thomas?
MR. THOMAS: Plaintiffs have identified Exhibit 14462, but this witness has a TVT-SECUR system which is a product that's not at issue in this case.
THE COURT: That's not a sufficient reason for me to sustain the objection. I don't have a question pending before the witness. The TVT, as I recall the testimony, in this case, is made out of exactly the same material as the TVT-O.
MR. THOMAS: Correct, Your Honor.
THE COURT: You may proceed.

(Sidebar concluded.)

BY MR. KUNTZ:

Q. Doctor, have you ever seen this document before?

A. I don't believe so.

Q. Okay. So you didn't look -- Ethicon's attorneys never gave you this document when you were forming your expert opinions in this case?

A. Like I said, sir, I'm a chemist and polymer scientist, and I looked at the characteristics of the chemical itself. I'm not a doctor. And this appears to me, from what I've seen here, this is a lot of information that physicians need to know about. I need to know about the polymeric material, Prolene and polypropylene.

Q. Okay.

A. I'm here to make a decision about that or opinions about that, not about medical issues.

Q. Well, if I'm not mistaken, in your direct you said the laser-cut and mechanical-cut mesh was exactly the same, and you pointed to some documents that it wasn't clinically significantly -- didn't have -- different. Do you remember that testimony?

A. I do.

Q. Okay. You've never seen this document before, have you?

A. Not to my knowledge --

Q. Okay.

A. -- as I sit here today.

MR. KUNTZ: Let's pull this document up, Evan.

THE COURT: Is it in evidence?

BY MR. KUNTZ:

Q. I'm sorry. Is this the type of document that -- well, you reviewed a clinical -- let me ask you this, Doctor. You're a scientist, right? This is a risk assessment. Do you know what a risk assessment is?

A. Yes, I believe so.

Q. And would this have been helpful to you in forming your opinions in this case, if you reviewed it?

A. Well, not really, in the sense that I really don't know what's in this document. But if there's not a lot of chemistry in here, if it doesn't talk about polypropylene and Prolene in terms of its reaction, in terms of chemical reactions that can occur, then with any factual data in there, it would not do me a great deal of good.

Q. Well, it talks about degradation 14 times. Is that relevant to your opinions?

A. Well, let's go through those 14 times, if you will, and I'll ask you -- I'll determine whether it is or not.

Q. So if it talks about degradation, it would be important to your opinions?

A. Well, can we look and see where those 14 times are?

Q. Go ahead and look.

A. Okay.

(Pause.)

BY MR. KUNTZ:

Q. Look at Page 5 of 17, there's a chart that talks about degradation.

A. Would that be 595, sir?

Q. Page 5 out of 17, it talks about Harms-hazard table.

A. I see the Harms-hazard table. That's Number 5?

Q. Right. Do you see the first harm is blood loss and across from it, it says, damage, degradation or deterioration in function. Do you see that? It's the first place it's mentioned.

THE COURT: Mr. Kuntz, could you stand a little closer to the microphone?

MR. KUNTZ: I apologize, Your Honor.

THE WITNESS: I'm sorry. I thought you were talking to me.

THE COURT: No, I was talking to Mr. Kuntz.

THE WITNESS: Would you repeat that, please?

BY MR. KUNTZ:

Q. My only question right now, Doctor, is this document discusses degradation. Do you understand that?

A. No, sir, because I haven't seen degradation yet. That's what I'm looking for.

Q. Okay. If you go to Page 5 -- because you haven't

reviewed this document before?
A. That's right.
Q. Okay. And you go to Page 5 of 17, there's a table called Harms-hazards table.
A. Okay.
Q. And if you go down to blood loss, it says, "Harm, blood loss," and then it says, "Related standardized hazards, damage, degradation or deterioration in the function." Do you see that?
A. I don't think I'm looking at the same chart you are.
MR. KUNTZ: May I approach, Your Honor?
THE COURT: You may.
BY MR. KUNTZ:
Q. Right there. (Indicating.)
A. Oh. Excuse me. Under "Blood loss," it says the harm, then it says, "Related standardized hazards, damage, degradation or deterioration in function."
Q. Okay. And my question is: If this document talks about degradation, it would be helpful to your opinions in this case, would it not, Doctor?
A. It depends on how they determined degradation, whether it's chemical degradation or degradation in the body for some other purpose, sir.
Q. Well, if Ethicon has an internal document talking about degradation being fair, reviewing all the information equally,

isn't it a document you'd like to have in forming your expert opinions in this case?

A. It certainly wouldn't hurt to read.

MR. KUNTZ: Okay. I will move for the admission of this document, Your Honor.

MR. THOMAS: Your Honor, there's no foundation for this document.

THE COURT: Well, it's -- based on that objection, I'll allow you to continue on the foundation. Do you have any more questions?

BY MR. KUNTZ:

Q. Dr. Thames --

A. I don't understand why blood loss is related to degradation.

Q. It doesn't -- doesn't that --

A. That doesn't resonate with me as a polymer scientist, sir.

Q. Does this document say that one of the related hazards --

MR. THOMAS: Objection, Your Honor.

THE COURT: Sustained.

Doctor, just listen to the question that he asks you and answer it if you can.

THE WITNESS: Okay, sir. Thank you.

THE COURT: Thank you.

THE WITNESS: Yes, sir.

BY MR. KUNTZ:

Q. Let's look on down the line of that chart, correct? Under "Exposure," on the next page, Page 6 of 17, under "Exposure," it says, "One of the related" --

MR. THOMAS: Objection, Your Honor.

THE COURT: You can't read it to him. You can do what you were doing before and you didn't get a straight answer. Try it again.

BY MR. KUNTZ:

Q. Doctor, wouldn't it be fair to your expert opinions in this case to have this document to review and to opine to this jury about degradation of mesh? When it discusses degradation 14 times?

MR. THOMAS: Objection, Your Honor.

THE COURT: Leading at the end. I sustain it.

Ask the question again without the leading. The jury will disregard.

BY MR. KUNTZ:

Q. Wouldn't this document discussing degradation of Ethicon's product be important to your opinions in this case, Dr. Thames?

THE COURT: You can lead on cross. You understand what I'm saying.

The question pending is: "Wouldn't this document discussing degradation of Ethicon's product be important to

your opinions in this case, Dr. Thames?"

THE WITNESS: If it had to do with a chemical function, yes, sir.

THE COURT: All right.

MR. KUNTZ: May I admit the document, Your Honor?

THE COURT: I haven't read the article, but if you're making the representation that it does, it may be admitted.

MR. THOMAS: It has chemical degradation?

THE COURT: Chemical properties, I think he said, but I'm not sure.

MR. THOMAS: I don't see it, Your Honor.

THE COURT: All right. You're going to have to let me see the article then.

MR. KUNTZ: Can we approach, Your Honor?

THE COURT: Sure.

(The following occurred at sidebar.)

MR. KUNTZ: Here is my position real quick. They took him outside his expert report and started talking about how different laser-cut and mechanical-cut mesh was and put up benchtop testing and showed the end of it that said it had no clinical significance, they are the same mesh. This is the laser-cut, the TVT-S that talks about all the potential hazards and harms, including degradation. This distinction between chemical degradation sure didn't come out on direct when he was an expert in all sorts of degradation.

THE COURT: Do you want to answer that?

MR. THOMAS: Yes, Your Honor.

The clinical expert report was put in as the final word on the benchtop testing. That's the only reason that I used it. And to the extent that anything came in incidentally on clinical issues, it's not what -- the reason why Dr. Thames is offered. Degradation in this paper, which I'll be honest with you, I'm not familiar with, talks about degradation without any kind of definition to it at all. It's not a chemical issue, it's not an oxidation issue, it's not a handling issue, it's not a misuse issue. Who knows what the degradation is here?

And it does not have anything to do with chemical degradation, by its terms, as Mr. Kuntz has shown the witness, from what I have been able to see.

THE COURT: You don't need to answer it. I'm going to rule in your favor.

MR. KUNTZ: Okay.

THE COURT: The document does in several places talk about the interaction of material with the tissue.

MR. THOMAS: Okay.

MR. KUNTZ: Thank you.

(Sidebar concluded.)

MR. KUNTZ: Plaintiffs would move to admit document 14462, Your Honor.

THE COURT: You may proceed. It may be admitted.
(PLAINTIFFS' EXHIBIT P-14462 WAS RECEIVED IN EVIDENCE.)
MR. KUNTZ: Do you want to pull that up?
(The document was published to the jury.)
BY MR. KUNTZ:
Q. Have you ever reviewed a risk assessment before, Dr. Thames?
A. No, sir.
Q. Do you know who wrote this document?
A. Yes, I believe there's some names here, but I don't know them. As I said, I haven't read this before.
Q. Do you know who Dr. Piet Hinoul is?
A. I think he's the medical director of Ethicon or --
Q. He's one of the authors of this document?
A. Yes.
Q. Okay. And let's look at -- turn to Page 5 of 17, correct? I'm sorry. Let's turn to Page 5 of 17, the Harms-hazard table we were discussing.
A. Okay.
Q. And you understand TVT-SECUR, which this document is about, uses the laser-cut mesh, correct?
A. That's what I understand, yes, sir.
Q. And so we're not talking about anybody else's polypropylene mesh that's out there in the universe. We're talking about Ethicon's polypropylene mesh. Correct?

A. Yes.
Q. Do you understand that? Okay.
And if you look in the blood loss section, it says, "Harms, blood loss, one of the related standardized hazards could be damage, degradation or deterioration in function." Do you see that?
A. I see it.
Q. Okay. So, according to Ethicon medical director Piet Hinoul and others who authored this, degradation --
MR. THOMAS: Objection, Your Honor.
BY MR. KUNTZ:
Q. -- degradation of Ethicon's mesh is possible?
MR. THOMAS: Argumentative, Your Honor.
THE COURT: What?
MR. THOMAS: Argumentative. That's not what it says.
THE COURT: Overruled.
THE WITNESS: I think that it says that that's what you want to look for, in terms of with blood loss. Do you have damage, degradation or deterioration, to determine if this is a risk and how severe it might be.
BY MR. KUNTZ:
Q. Okay.
A. They're not saying that's what happens, as I look at this.
Q. Ethicon's medical directors believed that degradation was

a possible risk for this product, correct?

MR. THOMAS: (Stands.)

THE COURT: Sustained.

THE WITNESS: That's not --

THE COURT: Whoa, whoa, whoa.

THE WITNESS: I'm sorry.

THE COURT: Sustained.

MR. THOMAS: You don't have to answer that.

BY MR. KUNTZ:

Q. But in this Ethicon document, we can agree, and I'll represent to you, degradation is mentioned 14 times, correct? Did you look at it earlier?

A. No, sir, I haven't counted 14 times.

Q. If we turn it over to the next page, Page 6 of 17, again, with exposure, we see damage, degradation, or deterioration in function, correct?

A. My answer would be the same.

Q. Okay.

A. They're looking at whether or not exposure is -- would provide damage, degradation, deterioration and trying to establish if it did, the severity ranking, as I see this document.

Q. So they believe degradation is a possibility?

MR. THOMAS: Objection, Your Honor.

THE COURT: Sustained. Jurors will disregard.

BY MR. KUNTZ:

Q. Do you remember talking about Plaintiffs' Exhibit 2028, the 1987 Prolene explant study?

A. Could I see it, please? Thank you.

Q. Do you agree that this -- have you reviewed this document? We talked about part of it on direct exam. Do you recall that?

A. I remember parts of it, yes.

Q. And they showed -- these explants show surface cracking, correct?

A. That's what they say was the case, but they did not -- did not identify where the cracking was from.

Q. And this was a study done by Ethicon, correct? The top of the first page, Ethicon, Inc., a Johnson & Johnson Company?

A. I'm going to have to take a minute to read this, sir. This is the first time I've seen this in a long, long time.

(The document was published to the jury.)

MR. THOMAS: (Stands.)

THE COURT: Yes, sir?

MR. THOMAS: Excuse me, Your Honor. This is not the same -- 2028, this is a different document than was shown on direct.

THE WITNESS: That's correct.

THE COURT: What is the number on this document?

BY MR. KUNTZ:

Q. Plaintiff's Exhibit 2028. You've reviewed this document before, haven't you?

THE COURT: I'm sorry. I'm sorry, just a minute. I hand you an exhibit that has a number on it. What is that number?

THE WITNESS: 2028.

THE COURT: All right. And plaintiffs' or defendants'? Does it say?

MR. KUNTZ: Plaintiffs'.

THE COURT: All right. That document has not been introduced.

MR. KUNTZ: Okay.

THE COURT: That doesn't mean it can't be. It just hasn't been.

MR. KUNTZ: My fault, Your Honor.

BY MR. KUNTZ:

Q. I've handed you what's been marked Plaintiffs' Exhibit 2028.

MR. THOMAS: May I have a copy, please?

BY MR. KUNTZ:

Q. Have you seen that document before, Dr. Thames?

A. It does not ring a bell as I look at it, sir.

Q. You never reviewed this document before?

A. As I look at it, I do not remember this document.

Q. Okay. Let's pull up -- we'll move on.

Let's pull up Plaintiffs' Exhibit 14102. This is the seven-year data for the dog study.

THE COURT: That's in, right?

THE DEPUTY CLERK: What's the number?

THE COURT: What's the number again?

MR. KUNTZ: I'm not sure of the defense numbering on it, but it's Plaintiffs' 14102.

THE COURT: Is it in evidence?

MR. THOMAS: Yes, Your Honor, two versions are in. Our version is a longer version. There are two versions in.

THE COURT: Okay. Is this one in? Or do we know? Give me the number again.

MR. KUNTZ: It's 141 --

THE COURT: I'm sorry to interrupt you, Mr. Kuntz. I'm just trying to keep your record for you here.

MR. KUNTZ: It's 10142.

THE COURT: Let me check. Just a second. It is not at the present time.

MR. KUNTZ: May I approach, Your Honor?

THE COURT: You may.

BY MR. KUNTZ:

Q. I'm going to hand you what's been marked Plaintiffs' Exhibit 14102.

A. All right.

Q. You reviewed -- you reviewed this document before,

haven't you, Dr. Thames?
A. Portions of it, yes, sir.
Q. And, in fact, we talked about portions of it on direct examination, correct?
A. Yes, sir.
Q. Okay. And this is the seven-year data from the dog study, correct?
A. It's some of seven-year data.
Q. And this was a study done by Ethicon, correct?
A. Yes, sir.
MR. KUNTZ: And if you -- we'll move to admit this, Your Honor.
MR. THOMAS: No objection, Your Honor.
THE COURT: It may be admitted.
(PLAINTIFFS' EXHIBIT P-14102 WAS RECEIVED IN EVIDENCE.)
(The document was published to the jury.)
MR. KUNTZ: Pull that up.
BY MR. KUNTZ:
Q. The first page, it's an Ethicon study, do you see that at the top?
A. Yes.
Q. Okay. And on the second page when we go to conclusions, it says, "Degradation in Prolene is still increasing." Do you see that?
A. That's what it says.

Q. And then it talks about "PVDF, even though a few cracks were found, it's still by far the most surface-resistant in-house made suture in terms of cracking," correct?
A. That's what it says.
Q. And PVDF has nothing to do with the polypropylene mesh that's in the TVT-O, correct?
A. That is correct.
Q. And that this study shows at seven years, "Degradation in Prolene is still increasing," correct?
A. That's what it says.
Q. And you disagree with that?
A. Absolutely.
Q. You disagree with Ethicon's study that says, "Degradation is still increasing"?
A. Absolutely.
Q. Dr. Thames, this is the first case you've testified about polypropylene, correct?
A. That is correct.
Q. Okay. Since you're now testifying in a case about polypropylene, are you following all the literature out there on polypropylene mesh?
A. Well, I wouldn't say all of it, but I followed some.
MR. KUNTZ: Okay. May I approach, Your Honor?
THE COURT: You may.
BY MR. KUNTZ:

Q. I'm going to hand you what's been marked Plaintiffs' Exhibit 21963. Have you ever seen this document before?
A. Give me just a moment, please.
Yes, I think I have.
Q. Okay. When did you review that document?
A. Several weeks ago.
Q. Did it help your opinions in this case?
A. Well, the part of this document that was really important to me was the fact that --
THE COURT: Is that a "yes"?
THE WITNESS: Yes, sir. Yes, sir.
BY MR. KUNTZ:
Q. Plaintiffs' --
A. Can I tell you why?
THE COURT: Well, just a second. I think he's going to move its admission.
THE WITNESS: Yes, sir.
MR. KUNTZ: Plaintiffs would move to admit 21963.
THE COURT: It may be received. You may proceed.
(PLAINTIFFS' EXHIBIT P-21963 WAS RECEIVED IN EVIDENCE.)
(The document was published to the jury.)
BY MR. KUNTZ:
Q. And, Dr. Thames, pull this up. The title of this is what?
A. It says, "In-depth nano-investigation of vaginal mesh and

tape fiber explants in women."

Q. Okay. And under "Results," if we go to that, it says, "Seven explants were studied covering a range of currently M/T devices (Gynemesh, TVT)," correct?

A. That's correct.

Q. And if we go down to the "Interpretations of results" section, do you see that?

A. Yes, I do.

Q. They start off with a discussion, "The results of this study," about four sentences down: "The results of this study point to significant physical degradation of the meshes for all those implanted for several reasons, while no chemical oxidation was observed."

A. I see that. And I note specifically there's a section that says, "No chemical oxidation was observed."

Q. But this study was done by doctors who took out meshes, correct?

A. That's right. And they talk about physical degradation.

Q. Okay. And they noticed that the mesh was degraded when they pulled it out of the body. That's their findings, correct?

A. I wouldn't use the term "degrade." It says, specifically, "The results of this study point to significant physical degradation," implying there is some physical forces that have caused the implant to change.

Q. Okay. So these doctors believe there's significant physical degradation. That's what they wrote, correct?
A. They wrote "physical degradation."
Q. Okay. And so you disagree with them on that account?
A. No, it is what it is. But it says, "There is no chemical oxidation or degradation," and that's what I've been testifying to today. I don't know how they treat it when people take them out with trocars and their clips and how they pull them out, I don't know how they treat it physically.
Q. So if there's been two doctors that have testified in this case that say they pulled out mesh and it looked degraded to them, to you that's not chemical degradation, correct?
A. I can't say, sir. I wasn't there, didn't see it.
Q. And These doctors that see degradation with the mesh, that's somehow done when they took it out, is that what you're telling the jury?
A. I'm sorry. I missed that statement.
Q. And the physical degradation that's here, you believe that that happened somehow in the surgery where they were taking the mesh out, correct?
A. That's too much information for me to answer at one step. You might want to start over, and I'll answer one at a time.
Q. You have no comment on whether there is physical degradation, correct?
A. I don't know.

Q. Okay. Doctor, we talked about several documents on your direct exam, or Mr. Thomas did, correct?
A. Yes, sir.
Q. Okay. Do you remember discussing D-21349?
A. I wouldn't know what that is, sir.
MR. KUNTZ: Let's pull that up. It's already been admitted.
(The document was published to the jury.)
BY MR. KUNTZ:
Q. And I think this was from Ethicon, some studies that discussed the opinion on the second page.
A. Yes, sir. I can hardly read that screen. Let me see if I can find the document here.
Q. Let me ask you this, Dr. Thames, and maybe shortcut this a little bit.
A. All right.
Q. You went through this document and you went through another one talking about benchtop testing in the clinical expert report; do you remember that?
A. Yes, I do.
Q. And you looked at all those and you went through with Mr. Thomas and you told the jury that supports your opinions that there's absolutely no difference between the laser-cut and mechanical-cut mesh, correct?
A. It's performs essentially the same, sir.

Q. And I think you said it performs the same way both scientifically and clinically, correct?
A. No, sir. I don't know about the clinical part. I know about the stiffness and the elongation of it, but I don't know anything about the body that a physician would understand. I'm a polymer scientist, sir.
Q. Okay. Did you ever talk to any of the doctors or ever ask any of this information of the doctors who use this mesh?
A. No, sir, I have not. I have not.
MR. KUNTZ: May I approach, Your Honor?
THE COURT: You may.
BY MR. KUNTZ:
Q. I'm going to hand you what's been marked 13055.
A. Yes, sir.
Q. Have you ever seen this document before?
A. I don't remember seeing it, sir.
Q. Okay. This wasn't on your reliance list, was it?
A. I don't remember seeing the document, sir.
Q. Ethicon's attorneys didn't give you this document to review, did they, in forming your opinions?
A. I don't remember seeing this document, sir.
Q. Have you had a chance to look over it?
A. No, sir.
Q. Okay. Why don't you take a minute to look over it.
A. Okay.

(Pause.)

THE WITNESS: All right, sir.

BY MR. KUNTZ:

Q. You reviewed that document, haven't you --

A. I have.

Q. -- Dr. Thames? And it talks about scientific --

MR. THOMAS: Objection, Your Honor.

BY MR. KUNTZ:

Q. It talks about scientific differences between laser-cut and mechanical-cut mesh, doesn't it?

MR. THOMAS: Objection, Your Honor.

THE COURT: Wait just a second.

That's innocuous enough. I'll overrule it. Is that the subject matter of the document?

THE WITNESS: No, sir, not the way I understand it.

THE COURT: All right.

MR. KUNTZ: Can we approach, Your Honor?

THE COURT: That was a responsive question, so you can ask another question.

BY MR. KUNTZ:

Q. Okay. Dr. Thames, does this document talk about the scientifical and theoretical calculations related to the laser-cut and mechanical-cut mesh?

A. The statement is specific. It says, "From a scientifically, but also clinical standpoint, it is

impossible," so forth. That's the term that's used.
Q. Okay. And so they're talking about the scientifical -- the benchtop testing, the stuff you talked about on direct, the differences between -- or non-differences between laser-cut and mechanical-cut mesh, correct?
A. No, they talk about theoretical calculations are not enough as evidence, and what we were talking about were not theoretical calculations. There was testing done.
Q. Not testing -- not testing in the body, correct?
A. No, testing was done, sir. This says, "Theoretical calculations are not enough as evidence." Theoretical calculations. That means there's no -- there's no lab top [sic] testing necessary. We were talking about lab benchtop testing.
Q. And when would that -- when was that benchtop testing done, in 2006, 2005?
A. I'm not sure. We'd have to look at those documents to see.
Q. I'll hand you the three documents you talked about on direct with those. What are the dates of all three of these?
THE COURT: Do you want to identify those real quick as exhibit numbers, please?
THE WITNESS: Do you want me to do that, sir?
THE COURT: Well, since you've got them, that would be handy, yeah.

THE WITNESS: 987, DX-21229.1, and DX-21350.1.

THE COURT: All right.

BY MR. KUNTZ:

Q. What are the dates of those three documents?

A. This is -- March 7 is the 350 document. May the 5th, '05 -- that was, by the way, '06. May the 5th, '05 is the 229.1 document. And March the 6th, '06 is the 349.1 document.

Q. All right. Are those all documents that -- and tests that were performed before laser-cut TVT-O went out on the market?

A. I'm sorry, I didn't understand your question.

Q. Were those all tests that were done before laser-cut TVT-O mesh was put out on the market?

A. Well, it was before this memorandum. This memorandum is in '08, I believe is the date on it.

Q. And that's after TVT-O laser-cut has been on the market, the document I've handed you, correct?

A. It's '08. Yes, sir.

Q. And the documents --

A. So these three documents, I can't tell you when it went on the market, sir. I don't know that.

Q. And the document I have handed you, which is Plaintiffs' Exhibit 13055, isn't that important in forming your opinions or the basis of your opinions in this case?

A. Let me find that document. 13055. Would you show me

that document again? Oh, is this it right here, sir?
Q. Another copy.
A. No, sir.
Q. So you don't have it?
A. No, sir.
Q. Sorry about that.
A. Sorry.
Q. I think I gave it to you.
A. You may have. Oh, yes, you did. My apologies. I was looking at the wrong number.
Question, please?
Q. This talks about Paragraph 2, scientifical standpoint, does it not?
A. Yes, sir.
Q. And that's the same type of studies you were talking about, scientifical is benchtop testing and clinical expert reports, you testified about on direct about laser-cut and mechanical-cut mesh, correct?
A. Yes, sir, but this --
THE WITNESS: Your Honor, I want to answer this question "yes" or "no," but there's phraseology in here that just doesn't allow me to do that. If I might share them with the Court.
THE COURT: Well, it's not in evidence yet because he hasn't moved it yet. So I don't know who's reading --

BY MR. KUNTZ:

Q. In making your expert opinions and testifying to this jury, don't you want to see all the documents from Ethicon that relate to the differences between laser-cut and mechanical-cut mesh, Doctor?

A. Well --

Q. Is there a question?

MR. THOMAS: Objection, Your Honor.

THE WITNESS: If it is a legitimate --

THE COURT: Overruled. You understood the question? All right. Go ahead.

THE WITNESS: I'm not sure I did, sir. I was reading this when he was asking me a question.

THE COURT: "In making your expert opinions and testifying to the jury, don't you want to see all of the documents from Ethicon that relate to the differences between laser-cut and mechanical-cut mesh, Doctor?"

THE WITNESS: Well, sure. That's important. I don't have a problem that.

THE COURT: All right. You may proceed.

BY MR. KUNTZ:

Q. And you understand this is an internal Ethicon e-mail, correct?

A. I do.

MR. KUNTZ: I would move to admit 13055, Your Honor.

MR. THOMAS: Objection, Your Honor.
THE COURT: What is the objection?
MR. THOMAS: There's still no foundation for this -- for this document.
THE COURT: Is it an e-mail?
MR. KUNTZ: Yes.
THE COURT: Let me see it. Let me see it.
(Pause.)
THE COURT: I will admit 13055, noting the defendants' objection.
(PLAINTIFFS' EXHIBIT P-13055 WAS RECEIVED IN EVIDENCE.)
BY MR. KUNTZ:
Q. This is the first time you've ever seen this document, isn't it, Dr. Thames?
A. As far as I know, yes, sir.
MR. KUNTZ: Let's go ahead and pull up Page 3 -- I'm sorry -- Page 2.
(The document was published to the jury.)
BY MR. KUNTZ:
Q. And this is an e-mail in 2008 between Ethicon employees. I will represent that to you. Do you understand that?
A. That's what it appears to be.
Q. Okay. And this is two years after TVT-O laser-cut mesh has been on the market; do you understand that?
A. I don't know when it went on the market. I think I've

stated that.
Q. And this is after the benchtop testing that we discussed earlier, two years, correct?
A. That's about right, yes, sir.
Q. And if we go down to the third paragraph, it starts with the word "then."
A. Third paragraph?
Q. Right.
MR. KUNTZ: Would you highlight that, Evan?
BY MR. KUNTZ:
Q. "Then it was decided that conversion was optional" -- and they're talking about the conversion from mechanical-cut mesh to laser-cut mesh. Do you understand that?
A. Yes, sir.
Q. -- "was optional to the markets, and in Scandinavia we got massive push back from our Key Opinion Leaders."
Do you know what a Key Opinion Leader is?
A. Not really.
Q. Okay.
A. Not in this context.
Q. I'll represent to you Key Opinion Leaders are doctors that consult with Ethicon. Do you understand that?
A. That sounds logical.
Q. Okay. "The main arguments from the likes of Carl Gustaf Nilsson." Do you know who Carl Gustaf Nilsson is?

A. No, sir.
Q. Do you know that he's the coinventor of the TVT line of products, Dr. Thames?
A. I don't know who he is, sir.
Q. Okay. I'm going --
A. I don't know that.
Q. He is the inventor of the TVT line of products. I will represent that to you as an officer of the court. Do you understand that?
MR. THOMAS: Your Honor --
THE COURT: Sustained. Just ask a question.
BY MR. KUNTZ:
Q. Do you know who Christian Faulkner is?
A. No, sir.
Q. And their comments on the difference between the mechanical-cut and laser-cut are -- say what? "From a scientifical, but also clinical standpoint, it is impossible and incorrect to say or assume that laser-cut would be the same as mechanically cut." Do you see that?
A. I see that.
Q. Okay. So you disagree with those two people as well, don't you?
A. Well, what I disagree with is the word "assumed." We did -- to assume anything is improper from a scientific perspective.

Q. Doctor, I'm sorry, but before that it says "impossible and incorrect to say or assume," right?
A. "Or assume."
Q. They're saying it's impossible and incorrect to say that the laser-cut mesh would be the same as mechanically-cut mesh from both a scientific standpoint and from a clinical standpoint, aren't they, Dr. Thames?
A. This is what they're saying, but I'm not sure they're aware of the testing that's been done. Perhaps they are not.
Q. Okay. So it's your position that Dr. Nilsson, who is just the -- one of the inventors of the TVT doesn't know about the benchtop testing?
A. I don't know whether --
MR. THOMAS: Objection.
THE COURT: Sustained, argumentative.
BY MR. KUNTZ:
Q. So you disagree, at least in this document, with what Dr. Nilsson and Dr. Faulkner are saying?
MR. THOMAS: Your Honor, that's three times.
THE COURT: It has been asked and answered, but you can answer it.
THE WITNESS: I don't disagree with what they say. I just don't know the context in which they're saying it, sir.
BY MR. KUNTZ:
Q. Okay. But you say the meshes are identical, correct?

A. From the point of view of the properties that were evaluated, the mechanical properties as a polymer scientist, yes, sir.
Q. And the inventors are saying they're not, correct?
MR. THOMAS: Objection, Your Honor.
THE COURT: Sustained. The jury will disregard.
BY MR. KUNTZ:
Q. They're not the same, are they?
MR. THOMAS: Objection, Your Honor.
THE COURT: Sustained.
MR. KUNTZ: No further questions.
THE COURT: All right. Redirect.
(REDIRECT EXAMINATION OF SHELBY THAMES, Ph.D. BY MR. THOMAS:)
Q. Dr. Thames, do you still have Exhibit 13055 in front of you?
A. One what, sir?
Q. 13055, that e-mail.
A. Yes, sir.
Q. You were asked quite a number of questions about this e-mail. Do the comments in this e-mail have anything to do with the kind of work that you were asked to do in this case?
A. Absolutely none.
Q. Okay. What, again, were you asked to do in this case?
A. I was asked to look at the chemistry of Prolene and polypropylene and determine whether or not it was sufficient

to be used as a polymeric system in the human body.
Q. And what were you asked to do with respect to the laser-cut mesh?
A. To determine whether or not it was properly evaluated, whether or not proper tests were run, to determine whether or not the tests were done properly, and so that these individuals could make a determination of what they did or did not want to use.
Q. And you've given the jury your opinions in that regard based on the testing that Ethicon actually did?
A. I have, sir.
Q. Do you have any idea what these people know about the testing?
A. No, I do not.
Q. Do these people's comments change your opinions about the testing that was actually done?
A. No, sir, not at all.
Q. Let's go to -- do you know whether these people were even aware of testing?
A. I think I implied that I don't know if they were or not.
Q. Let's go to Plaintiffs' Exhibit 893, the PA Consulting report. Do you have that in front of you, sir?
A. I think I can find it.
MR. THOMAS: I need you to go to Page 35.
(The document was published to the jury.)

THE WITNESS: I'll just use this one. It's easier.
MR. THOMAS: Is it up on the screen, Jamey? It's 893.
THE WITNESS: It's up on my screen.
BY MR. THOMAS:
Q. Page 35, do you have that in front of you?
A. It doesn't --
Q. Is it on your screen?
A. Yes, sir, 35.
Q. And Mr. Kuntz asked you about "Polypropylene can suffer from degradation following implant," that's the title there, isn't it?
A. Yes, sir.
Q. And the first bullet point reads: "Polypropylene has a long history of use, but it is subject to degradation, a process which initiates after a few days postimplantation in animal studies."
Did I read that correctly?
A. You did.
Q. Does this say "Prolene polypropylene"?
A. No, sir. Does not.
Q. Okay. Now, it cites to a footnote, doesn't it?
A. Yes, it does.
Q. And what's the footnote it cites to?
A. Liebert.

Q. And you talked with the jury about Liebert this morning, didn't you?
A. I did.
Q. And remind the jury what you said about the Liebert article.
A. Mr. -- Dr. Liebert actually made his own polypropylene, and he extruded it and he added antioxidants to Sample A and he put no antioxidants in Sample B. So he didn't use Ethicon's material. He just used polypropylene without any additives, and as a matter of fact, the one that oxidized had no antioxidants in it. So this is a completely different set of circumstances than we're dealing with today.
Q. Based on Liebert, what happens when you have polypropylene that has an appropriate antioxidant package in it?
A. No oxidation occurs, no molecular weight changes. He stops talking about it when he realized that there's no changes going to take place.
Q. All right. Let's go to Plaintiffs' Exhibit 21963, please. This is the nano-investigation document you were just --
A. Yes, sir.
Q. About the doctors who apparently had looked at some explants and talked about physical degradation.
A. Yes, sir.

Q. When you talk about physical degradation, of what significance is that to you as a polymer scientist?
A. Well, I can take a pair of tongs or tweezers or a pair of pliers, and I can pull something and I can physically degrade it. You know, it depends upon how kindly I treat the material. Physical degradation is quite different than chemical degradation. We've been talking about chemical degradation here today.
Q. And what did -- did they do any analytical chemistry tests in that report?
A. No, not that I can tell.
Q. What's this Raman spectroscopy that's referenced at the bottom of the results? The last line, says, "Raman spectroscopy did not reveal any major variation in the chemical properties of the polypropylene fibers, especially no new peaks for oxidation"?
A. It's another form of infrared spectroscopy or the type of spectroscopy and it's good with some materials and it's good for this material. So it's another way of looking at whether there has been compositional exchanges or not.
Q. What does that tell you the extent to which the polypropylene in this study degraded in terms of a change in chemical structure?
A. It didn't. No change.
Q. So does this study, Plaintiffs' 21963, stand for the

proposition that these explants underwent a change in the chemical structure of the polypropylene?

A. No, sir.

Q. Now, do they measure molecular weight?

A. No.

Q. Do they measure tensile strength?

A. No.

Q. Do you know whether it was stored in formalin?

A. I do not know.

Q. And why are those things important to know as well?

A. We talked about it. Molecular weight is changed and there has been degradation. If you have no molecular weight determinations, if it hasn't changed, there is -- you know if it hasn't changed, you can't say there has been any degradation, because there has not.

And if it's stored in formalin then it's an opportunity for the protein formaldehyde polymer to form around it, form a brittle, amorphous structure that -- that will interfere with your testing results and with your FTIR data, so none of that was done here.

Q. And you were also shown on cross-examination Plaintiffs' Exhibit 14462, the risk assessment summary for the Gynecare TVT-SECUR system where the word "degradation" is used?

A. Yes, sir.

Q. Do you have any idea of the context of the use of that

word?
A. No, sir. I could take a scientific guess, so to speak, but I -- I think I know, but I don't really understand what they're trying to do here.
Q. Is there anything about what you reviewed in 14462, Plaintiffs' Exhibits 14462, that impacts your opinions at all about whether Prolene polypropylene degrades?
A. Not at all.
Q. Tell me why.
A. Well, it doesn't have anything to do with the physical properties. It doesn't have anything to do with the chemistry. It talks about what-ifs, and we've talked about the scientific properties of polypropylene and made into Prolene, and we found out that it doesn't change molecular weight when you implant it in -- in the case we've talked about is in terms of dogs, we found out there's no change in the mechanical properties, except for the good. The polymer gets tougher when it's implanted in the animals. There is -- there is no -- no indication, no scientific data that says polypropylene oxidizes or degrades. Period.
Q. Now, you also were asked some questions about the Mary Céline article, and I'm sorry, I don't have the plaintiffs' exhibit number. Do you have that in front of you?
A. I've got the article up here. I'll just have to find it.
MR. KUNTZ: 14114.

MR. THOMAS: Thank you.

BY MR. THOMAS:

Q. Plaintiffs' Exhibit 14114. Did you have the data that the doctors in the Mary Céline article utilized in preparing that report?

A. No, sir.

Q. And why is that a problem to you to understand what they did?

A. Well, for instance, if you look at infrared, they don't show the infrared spectra. They just say here's where there was absorption frequencies. And it's important to me that, as a scientist, that when I look at -- at a peer-reviewed article, I expect to see the data from which the conclusion is drawn. I don't want to just see the conclusion. It doesn't mean anything to me if I don't have the supporting background data to form the conclusions.

Q. In the Mary Céline article, did they measure molecular weight?

A. No, sir.

Q. Do they measure tensile strength?

A. No, sir.

Q. Do they measure elongation?

A. No, sir.

Q. Do you have enough information about the sample preparation to know whether the sample could have been

compromised in the tests that they did?
A. Well, I know that they tried to clean it. I know that they treated it with formaldehyde and glutaraldehyde, so there has been this -- this formation of protein aldehyde composite around the fibers, and that has the ability to interfere, and when it dries, it cracks, and you see that under scanning electron microscope, you see the cracks.
Q. Is there anything about the documents that were shown to you by Mr. Kuntz on cross-examination that impacts the opinions that you gave to the jury this morning?
A. No, sir.
MR. THOMAS: Thank you, Your Honor.
THE COURT: May the witness be excused?
MR. KUNTZ: Yes, Your Honor.
THE COURT: Thank you, Doctor, you're excused.
Call your next witness.
MS. JONES: Your Honor, at this time we would call Dr. Aaron Kirkemo, by deposition. And if we could approach just one second, Your Honor.
THE COURT: Sure.
(A sidebar discussion was held off the record.)
THE COURT: Ladies and gentlemen of the jury, the next testimony will be by video deposition. This testimony is a witness called by the defendant, but the testimony is going to first have the questions by the plaintiff and then the

defendant. Don't pay any attention to the order in which it's -- the questioning comes in. Just listen to all of the evidence. Give it the same weight you would as if the witness were testifying here today. You may proceed.

(The video testimony of Dr. Aaron Kirkemo was played at 2:16 p.m.)

THE COURT: Can we take a break here? Let's take our afternoon break. Ladies and gentlemen, during the break, do not discuss the case among yourselves, allow anyone to discuss it with you, don't use any social media, listen to anything, study anything or read anything.

See you back in 15 minutes. Court stands in recess.

(The jury left the courtroom at 3:05 p.m.)

THE COURT: Court is in recess.

(A recess was taken at 3:05 p.m.)

(The jury entered the courtroom at 3:20 p.m.)

THE COURT: Ladies and gentlemen of the jury, we're going to finish this videotape which has got a ways to go, and then we have one more witness by videotape and we're going to finish that today too.

Let's go.

(The video testimony of Aaron Kirkemo, M.D. continued.)

MR. WALLACE: Your Honor, we believe we need about two more minutes to reboot.

THE COURT: That's fine. This trial has been freer of technical glitches than almost anything I had.

(The video testimony of Aaron Kirkemo, M.D. continued.)

MS. JONES: That's it, Your Honor.

THE COURT: I had said we were going to have another witness, but it's after five o'clock now, so we're not. We're going to break for the evening. We'll start right at 9:00 o'clock. Please do not discuss the case amongst yourselves or permit anyone to discuss it with you. Don't answer any questions by family members. Don't watch anything on local TV news, don't read the local newspapers, don't listen to anything about this case. Don't use social media or computers to do any research or any other methodology. Forget about case until tomorrow morning. Have a nice evening, I'll see you at 9:00 o'clock.

Counsel remain, please.

(The jury left the courtroom at 5:05 p.m.)

THE COURT: I have an independent responsibility to give a proper charge to the jury above and beyond the suggestions which counsel always helpfully make to me as to the contents of the charge, and in that regard there are a number of things that are rattling around in my head about products liability law and obviously about this product and this case in particular. Now, I would like your help, and by

that I don't mean big long briefs, I mean well thought-out short statements of logical argument or support.

One of the things I think that might be helpful is if you would address for me briefly the applicability of comment K of restatement 402A to the facts of this case as it has developed at trial.

Secondly, and perhaps more confused is the difficulty I have with two legal concepts and settled principles seemingly to being at odds in the way the case is right now; and I need you to tell me if they are or they aren't, and if they are, what to do about it, and if they aren't, what to do about it.

The testimony in this case from all of the medical witnesses has been that the use of the TVT-O by urologists and other qualified physicians for the treatment of stress urinary incontinence meets the standard of care. I think even one of the plaintiffs' doctors when asked that question said it met the standard of care for a doctor to use. If I'm wrong on that, please point out where I'm wrong.

How can use of a device meet the standard of care and still be unreasonably dangerous, which it must be under the strict liability tort? For that matter, how can a device which meets the standard of care, if it does, when used by a qualified physician, be negligent in its manufacture? That is to say, how can a device which is deemed the proper standard

device for the care of this problem be deemed negligently designed or unreasonably dangerous?

Failure to warn is an easier concept for me to wrap my head around. I think I got that. But I wonder, I wonder a little bit, you don't have enough lawyers, I know you got lots of lawyers, but you don't have enough lawyers to give me this by tomorrow, so I won't go overboard, I'll just tell you what I'm thinking about just so you'll know.

Is there a different measure or standard, if you will, for proper warning where a medical device is extraordinarily dangerous? In other words, if you get back to the comment that I asked you to brief, does it have any relevance, does that comment have any relevance in failure to warn claims? It's not brought up in that context, but I just wonder, does one have a further obligation?

You know, with drugs and regulated products, we have black box warnings and all those things. Is there any concept here that says -- I don't think I can go on and make any sense. I think if you'll ignore the last two minutes and give me the information I asked for in the beginning, that would be very helpful to me.

There is clearly evidence before this court from witnesses who qualified to testify and give their opinions that they wouldn't use this device, that they have the expert opinion that other devices meet the gold standard, and that

they believe the device is, one witness, one expert witness said dangerously defective, one of plaintiffs' expert witnesses.

I'm not throwing all this out there just to confuse the issue for the evening because you got witnesses to deal with and other things, but those are the things I'm thinking about when I've got to instruct the jury, or when I've got to ask them interrogatories. So have a nice evening. See you back here tomorrow morning.

Why don't you come at 8:30 if you come up with any wonderful ideas and you want to share them with me orally, I'll listen to you then, okay? Have a nice night.

(The Judge left the courtroom at 5:14 p.m.)

(A recess was taken at 5:14 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Anthony Rolland, CRR, RMR, RPR,** do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR **09/02/14**
Court Reporter **Date**

/S/ Anthony Rolland, CRR, RMR, RPR **09/02/14**
Court Reporter **Date**